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[1] Text with EEA relevance

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

EN

[1] Text with EEA relevance

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

REGULATION (EC) No 762/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 July 2008

on the submission by Member States of statistics on aquaculture and repealing Council Regulation (EC) No 788/96

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 285(1) thereof,

Having regard to the proposal from the Commission,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ([1]),

Whereas:

(1) Council Regulation (EC) No 788/96 of 22 April 1996 on the submission by Member States of statistics on aquaculture production ([2]) requires the Member States to submit annual data on the volume of production.

(2) The increased contribution by aquaculture to the Community's total fisheries production requires a wider range of data for a rational development and management of this sector within the Common Fisheries Policy.

(3) The increasing importance of hatcheries and nurseries for aquaculture activity requires detailed data for a suitable monitoring and management of this sector within the Common Fisheries Policy.

(4) Information on both the volume and value of the production is required to review and assess the market for aquaculture products.

(5) Information on the structure of the sector and on the technologies employed is required to ensure an environmentally sound industry.

(6) Regulation (EC) No 788/96 should be repealed.

(7) In order to ensure a smooth transition from the regime applicable under Regulation (EC) No 788/96, this Regulation should allow for a transitional period of up to three years to be granted to Member States where its application to their national statistical systems would require major adaptations and would be likely to cause significant practical problems.

(8) Since the objective of this Regulation, namely the establishment of a common legal framework for systematic production of Community statistics on the aquaculture sector, cannot be sufficiently achieved by the Member States and can be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(9) Council Regulation (EC) No 322/97 of 17 February 1997 on Community Statistics ([3]) provides a reference framework for statistics in the field of fisheries. In particular, it requires conformity with principles of impartiality, reliability, relevance, cost-effectiveness, statistical confidentiality and transparency.

(10) The collection and submission of statistical data is an essential tool for the sound management of the Common Fisheries Policy.

([1]) Opinion of the European Parliament of 31 January 2008 (not yet published in the Official Journal) and Council Decision of 23 June 2008.

([2]) OJ L 108, 1.5.1996, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

([3]) OJ L 52, 22.2.1997, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council.

(11) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([1]).

(12) In particular, the Commission should be empowered to adopt technical changes to the Annexes to this Regulation. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(13) The Commission should be assisted by the Standing Committee for Agricultural Statistics set up by Council Decision 72/279/EEC ([2]),

HAVE ADOPTED THIS REGULATION:

Article 1

Obligations of the Member States

Member States shall submit to the Commission statistics on all the aquaculture activities conducted in freshwater and saltwaters on their territory.

Article 2

Definitions

1. For the purpose of this Regulation, the following definitions shall apply:

(a) 'Community statistics' as defined in Article 2 of Regulation (EC) No 322/97;

(b) 'aquaculture' as defined in Article 3(d) of Council Regulation (EC) No 1198/2006 of 27 July 2006 on the European Fisheries Fund ([3]);

(c) 'capture-based aquaculture' means the practice of collecting specimens from the wild and their subsequent use in aquaculture;

(d) 'production' means the output from aquaculture at first sale, including production from hatcheries and nurseries offered for sale.

2. All other definitions for the purpose of this Regulation are set out in Annex I.

Article 3

Compilation of statistics

1. Member States shall use surveys or other statistically validated methods covering at least 90 % of the total production by volume, or by number for the production of hatcheries and nurseries, without prejudice to paragraph 4. The remaining part of the total production may be estimated. To estimate more than 10 % of the total production, a request for derogation may be submitted under the conditions provided for in Article 8.

2. Use of sources other than surveys shall be subject to provision of an *ex-post* assessment of the statistical quality of those sources.

3. A Member State having a total annual production of less than 1 000 tonnes may submit summary data estimating the total production.

4. Member States shall identify the production by species. However, the production of those species which individually do not exceed 500 tonnes and do not represent more than 5 % in weight of the production by volume in a Member State may be estimated and aggregated. The production of hatcheries and nurseries in number of those species may be estimated.

Article 4

Data

The data shall relate to the reference calendar year and shall cover:

(a) the annual production (volume and unit value) of aquaculture;

(b) the annual input (volume and unit value) to capture-based aquaculture;

(c) the annual production of hatcheries and nurseries;

(d) the structure of the aquaculture sector.

Article 5

Submission of data

1. The Member States shall submit the data referred to in Annexes II, III and IV to the Commission (Eurostat) within 12 months of the end of the reference calendar year. The first reference calendar year shall be 2008.

2. Starting with the data for the year 2008 and at intervals of three years thereafter, the data on the structure of the aquaculture sector referred to in Annex V shall be submitted within 12 months of the end of the reference calendar year to the Commission (Eurostat).

Article 6

Quality assessment

1. Each Member State shall provide the Commission (Eurostat) with a yearly report on the quality of the data submitted.

([1]) OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).
([2]) OJ L 179, 7.8.1972, p. 1.
([3]) OJ L 223, 15.8.2006, p. 1.

2. At the submission of the data, each Member State shall submit to the Commission a detailed methodological report. In that report, each Member State shall describe how the data were collected and compiled. This report shall include details of sampling techniques, estimation methods and of sources used other than surveys and an evaluation of the quality of the resultant estimates. A proposed format for the methodological report is indicated in Annex VI.

3. The Commission shall examine the reports and present its conclusions to the relevant working group of the Standing Committee for Agricultural Statistics set up by Decision 72/279/EEC.

Article 7

Transitional period

1. Full calendar year transitional periods for implementing this Regulation lasting not more than three years from 1 January 2009 may be granted to Member States in accordance with the management procedure referred to in Article 10(2), in so far as the application of this Regulation to their national statistical systems requires major adaptations and is likely to cause significant practical problems.

2. To this end, a Member State shall present a duly motivated request to the Commission by 31 December 2008.

Article 8

Derogations

1. In cases where inclusion in the statistics of a particular sector of aquaculture activities would cause difficulties to the national authorities not commensurate with the importance of that sector, a derogation may be granted in accordance with the management procedure referred to in Article 10(2).

Such derogation shall permit a Member State to exclude data covering that sector from the national data submitted or to employ estimation methods used to provide data for more than 10 % of the total production.

2. Member States shall support any request for derogations, which must be made prior to the deadline for the first submission of the data, by sending the Commission a report on problems encountered in applying this Regulation.

3. Should a change in the situation for collecting the data create unforeseen difficulties for the national authorities, a duly justified request for a derogation may be submitted by the Member States after the deadline for the first submission of the data.

Article 9

Technical provisions

1. The measures designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, relating to technical changes to the Annexes shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(3).

2. The format in which statistics shall be submitted shall be adopted in accordance with the management procedure referred to in Article 10(2).

Article 10

Committee procedure

1. The Commission shall be assisted by the Standing Committee for Agricultural Statistics.

2. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 11

Evaluation report

By 31 December 2011 and every three years thereafter, the Commission shall submit an evaluation report to the European Parliament and to the Council on the statistics compiled pursuant to this Regulation and, in particular, on their relevance and quality.

This report shall also undertake a cost-effectiveness analysis of the system introduced to collect and draw up the statistics and shall indicate best practices to lessen the workload for Member States and enhance the usefulness and quality of the data.

Article 12

Repeal

1. Without prejudice to paragraph 3, Regulation (EC) No 788/96 is hereby repealed.

2. References to the repealed Regulation shall be construed as references to this Regulation.

3. By way of derogation from the second paragraph of Article 13 of this Regulation, a Member State having been granted a transitional period in accordance with Article 7 of this Regulation shall continue to apply the provisions of Regulation (EC) No 788/96 for the duration of the transitional period granted.

Article 13

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2009.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 9 July 2008.

For the European Parliament	*For the Council*
The President	*The President*
H.-G. PÖTTERING	J.-P. JOUYET

ANNEX I

Definitions to be used in submission of aquaculture data

1. 'Freshwater' means water which has a constantly negligible salinity.

2. 'Saltwater' means water where the salinity is appreciable. This may be water where the salinity is constantly high (e.g. seawater) or where the salinity is appreciable but not at a constantly high level (e.g. brackish water): the salinity may be subject to periodic variation due to the influx of fresh or seawaters.

3. 'Species' means the species of aquatic organisms identified using the international 3-alpha code as defined by the FAO (ASFIS list of species for fishery statistics purposes).

4. 'FAO major areas' means the geographical areas identified using the international numerical-2 code as defined by the FAO (CWP Handbook of fishery statistical standards. Section H: Fishing areas for statistical purposes). The FAO major areas covered for the purpose of this Regulation are the following:

Code	Area
01	Inland waters (Africa)
05	Inland waters (Europe)
27	North-east Atlantic
34	Atlantic Eastern Central
37	Mediterranean and Black Seas
…	Other areas (to be specified)

5. 'Ponds' means relatively shallow and usually small bodies of still water or water with a low refreshment rate, most frequently artificially formed, but can also apply to natural pools, tarns, meres or small lakes.

6. 'Hatcheries and nurseries' means places for the artificial breeding, hatching and rearing through the early life stages of aquatic animals. For statistical purposes, hatcheries are limited to the production of fertilised eggs. First juvenile stages of aquatic animals are considered as being produced in nurseries.

7. 'Enclosures and pens' means areas of water confined by nets, mesh and other barriers allowing uncontrolled water interchange and distinguished by the fact that enclosures occupy the full water column between substrate and surface; pens and enclosures generally enclose a relatively large volume of water.

8. 'Cages' means open or covered enclosed structures constructed with net, mesh or any porous material allowing natural water interchange. These structures may be floating, suspended or fixed to the substrate but still permitting water interchange from below.

9. 'Tanks and raceways' means artificial units constructed above or below ground level capable of high rates of water interchange or with a high water turnover rate and highly controlled environment but without water recirculation.

10. 'Recirculation systems' means systems where the water is reused after some form of treatment (e.g. filtering).

11. 'Transferred to a controlled environment' means the intentional release for further aquaculture practices.

12. 'Released to the wild' means the intentional release for the restocking of rivers, lakes and other waters other than for aquaculture purposes. These releases may then be available for capture by fishing operations.

13. 'Volume' means:

(a) for fish, crustaceans and molluscs and other aquatic animals, the live weight equivalent of the product. For molluscs, the live weight shall include the weight of the shell;

(b) for aquatic plants, the wet weight of the product.

14. 'Unit value' means the total value (excluding invoiced value-added tax) of the production (in national currency) divided by the total volume of the production.

ANNEX II

Production from aquaculture excluding nurseries and hatcheries [a]

Country: Year:

Species produced				FAO major area	Freshwater		Saltwater		Total	
	3-alpha code	Common name	Scientific name		Volume (metric tonnes)	Unit value (national currency)	Volume (metric tonnes)	Unit value (national currency)	Volume (metric tonnes)	Unit value (national currency)
FISH										
Ponds										
Tanks and raceways										
Enclosures and pens										
Cages										
Recirculation systems										
Other methods										
CRUSTACEANS										
Ponds										
Tanks and raceways										
Enclosures and pens										
Other methods										
MOLLUSCS										
On bottom										
Off bottom										
Other methods										
SEAWEEDS										
All methods										

Country: Year:

Species produced				FAO major area	Freshwater		Saltwater		Total	
	3-alpha code	Common name	Scientific name		Volume (metric tonnes)	Unit value (national currency)	Volume (metric tonnes)	Unit value (national currency)	Volume (metric tonnes)	Unit value (national currency)
Fish eggs (intended for consumption) [b]										
All methods										
OTHER AQUATIC ORGANISMS										
All methods										

[a] With the exclusion of aquarium and ornamental species.
[b] The fish eggs intended for consumption considered under this item refer only to extracted eggs destined for consumption at first sale.

ANNEX III

Input to capture-based aquaculture [a]

Country: Year:

Species			Unit (specify) [b]	Unit value (national currency)
3-alpha code	Common name	Scientific name		
FISH				
CRUSTACEANS				
MOLLUSCS				

[a] With the exclusion of aquarium, ornamental and plant species.
[b] Weight or number; if numbers are provided, a conversion factor to live weight must be provided as well.

ANNEX IV

Production of hatcheries and nurseries [a]

Country: Year:

Species			Stage in life cycle		Intended uses			
3-alpha code	Common name	Scientific name	Eggs (in millions)	Juveniles (in millions)	Transferred to a controlled environment (for on-growing) [b] (in millions)		Released to the wild [b] (in millions)	
					Eggs	Juveniles	Eggs	Juveniles

[a] With the exclusion of aquarium and ornamental species.
[b] Voluntary.

ANNEX V

Data on the structure of the aquaculture sector [a] [d]

Country: Year:

	FAO major area	Freshwater		Saltwater		Total	
		Size of the facilities [c]		Size of the facilities [c]		Size of the facilities [c]	
		(thousand m^3)	Hectares	(thousand m^3)	Hectares	(thousand m^3) Hectares	
FISH							
Ponds							
Tanks and raceways							
Enclosures and pens							
Cages							
Recirculation systems							
Other methods							
CRUSTACEANS							
Ponds							
Tanks and raceways							
Enclosures and pens							
Other methods							
MOLLUSCS							
On bottom [b]							
Off bottom [b]							
Other methods [b]							

Country: Year:

	FAO major area	Freshwater		Saltwater		Total	
		Size of the facilities [c]		Size of the facilities [c]		Size of the facilities [c]	
		(thousand m^3)	Hectares	(thousand m^3)	Hectares	(thousand m^3) Hectares	
SEAWEEDS							
All methods							

[a] With the exclusion of aquarium and ornamental species.
[b] If molluscs are grown on ropes, length unit may be used.
[c] Should be considered the potential capacity.
[d] The shaded cells indicate where information is not applicable.

ANNEX VI

Format for the methodological reports of the national systems for aquaculture statistics

1. Organisation of the national system for aquaculture statistics:

   — authorities responsible for collecting and processing the data and their respective responsibilities,

   — national legislation on the collection of aquaculture data,

   — unit responsible for submitting data to the Commission.

2. Method of collecting, processing and compiling the aquaculture data:

   — indicate the source of each type of data,

   — describe the methods used to collect the data (e.g. postal questionnaires, personal interviews, censuses or sampling, frequency of surveys, estimation methods) for each part of the aquaculture sector,

   — describe how the data are processed and compiled and how long this takes.

3. Quality aspects in line with the 'Code of Practice for the European Statistical System':

   — if estimation techniques are used for some elements of the data, describe the methods used, and estimate the level of use and reliability of such methods,

   — indicate any shortcomings of the national systems, ways of overcoming them and, where appropriate, the timetable for such corrective actions.

REGULATION (EC) No 763/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 July 2008

on population and housing censuses

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 285(1) thereof,

Having regard to the proposal from the Commission,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ([1]),

Whereas:

(1) The Commission (Eurostat) needs to be in possession of sufficiently reliable, detailed and comparable data on the population and housing, in order to enable the Community to fulfil the tasks assigned to it, in particular by Articles 2 and 3 of the Treaty. Sufficient comparability must be ensured at Community level as regards methodology, definitions and the programme of the statistical data and the metadata.

(2) Periodic statistical data on the population and the main family, social, economic and housing characteristics of persons are necessary for the study and definition of regional, social and environmental policies affecting particular sectors of the Community. In particular, there is a need to collect detailed information on housing in support of various Community activities, such as the promotion of social inclusion and the monitoring of social cohesion at regional level, or the protection of the environment and the promotion of energy efficiency.

(3) In view of methodological and technological developments, best practices should be identified and the enhancement of the data sources and methodologies used for censuses in the Member States should be fostered.

(4) In order to ensure the comparability of the data provided by the Member States and for reliable overviews to be drawn up at Community level, the data used should refer to the same reference year.

(5) In accordance with Council Regulation (EC) No 322/97 of 17 February 1997 on Community Statistics ([2]), which constitutes the reference framework for the provisions of this Regulation, it is necessary for the collection of statistics to conform to the principles of impartiality, in particular objectivity and scientific independence, as well as transparency, reliability, relevance, cost-effectiveness and statistical confidentiality.

(6) The transmission of data subject to statistical confidentiality is governed by Regulation (EC) No 322/97 and Council Regulation (Euratom, EEC) No 1588/90 of 11 June 1990 on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities ([3]). Measures that are taken in accordance with those Regulations ensure the physical and logical protection of confidential data and that no unlawful disclosure or non-statistical use occurs when Community statistics are produced and disseminated.

(7) In the production and dissemination of Community statistics under this Regulation, the national and Community statistical authorities should take account of the principles set out in the European Statistics Code of Practice adopted on 24 February 2005 by the Statistical Programme Committee, established by Council Decision 89/382/EEC, Euratom ([4]) and attached to the Recommendation of the Commission on the independence, integrity and accountability of the national and Community statistical authorities.

(8) Since the objectives of this Regulation, namely the collection and compilation of comparable and comprehensive Community statistics on population and housing, cannot be sufficiently achieved by the Member States, due to the absence of common statistical features and quality requirements as well as a lack of methodological transparency, and can therefore, by way of a common statistical framework, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

([1]) Opinion of the European Parliament of 20 February 2008 (not yet published in the Official Journal) and Council Decision of 23 June 2008.

([2]) OJ L 52, 22.2.1997, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

([3]) OJ L 151, 15.6.1990, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003.

([4]) OJ L 181, 28.6.1989, p. 47.

(9) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([1]).

(10) In particular, the Commission should be empowered to establish the conditions for the establishment of subsequent reference years and the adoption of the programme of the statistical data and the metadata. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(11) The Statistical Programme Committee has been consulted in accordance with Article 3 of Decision 89/382/EEC, Euratom,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation establishes common rules for the decennial provision of comprehensive data on population and housing.

Article 2

Definitions

For the purpose of this Regulation, the following definitions shall apply:

(a) 'population' shall mean the national, regional and local population at its usual residence at the reference date;

(b) 'housing' shall mean living quarters and buildings as well as housing arrangements and the relationship between the population and living quarters at the national, regional and local levels at the reference date;

(c) 'buildings' shall mean permanent buildings that contain living quarters designed for human habitation, or conventional dwellings that are reserved for seasonal or secondary use or that are vacant;

(d) 'usual residence' shall mean the place where a person normally spends the daily period of rest, regardless of temporary absences for purposes of recreation, holidays, visits to friends and relatives, business, medical treatment or religious pilgrimage.

The following persons alone shall be considered to be usual residents of the geographical area in question:

(i) those who have lived in their place of usual residence for a continuous period of at least 12 months before the reference date; or

(ii) those who arrived in their place of usual residence during the 12 months before the reference date with the intention of staying there for at least one year.

Where the circumstances described in point (i) or (ii) cannot be established, 'usual residence' shall mean the place of legal or registered residence;

(e) 'reference date' shall mean the date to which the data of the respective Member State refer, in accordance with Article 5(1);

(f) 'national' shall mean on the territory of a Member State;

(g) 'regional' shall mean at NUTS level 1, NUTS level 2 or NUTS level 3, as defined in the classification of territorial units for statistics (NUTS), established by Regulation (EC) No 1059/2003 of the European Parliament and of the Council ([2]) in its version applicable at the reference date;

(h) 'local' shall mean at Local Administrative Units level 2 (LAU level 2);

(i) 'essential features of population and housing censuses' shall mean individual enumeration, simultaneity, universality within a defined territory, availability of small-area data and defined periodicity.

Article 3

Data submission

Member States shall submit to the Commission (Eurostat) data on the population covering determined demographic, social and economic characteristics of persons, families and households, as well as on housing at a national, regional and local level, as set out in the Annex.

Article 4

Data sources

1. Member States may base the statistics on different data sources, in particular on:

(a) conventional censuses;

(b) register-based censuses;

(c) a combination of conventional censuses and sample surveys;

(d) a combination of register-based censuses and sample surveys;

(e) a combination of register-based censuses and conventional censuses;

([1]) OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

([2]) OJ L 154, 21.6.2003, p. 1. Regulation as last amended by Regulation (EC) No 176/2008 of the European Parliament and of the Council (OJ L 61, 5.3.2008, p. 1).

(f) a combination of register-based censuses, sample surveys and conventional censuses; and

(g) appropriate surveys with rotating samples (rolling censuses).

2. Member States shall take all measures necessary to meet the requirements of data protection. The Member States' own data protection provisions shall not be affected by this Regulation.

3. Member States shall inform the Commission (Eurostat) of any revision or correction of the statistics supplied under this Regulation, as well as of any changes in the chosen data sources and methodology, no later than one month before the release of the revised data.

4. Member States shall ensure that the data sources and the methodology used to satisfy the requirements of this Regulation meet, to the highest possible extent, the essential features of population and housing censuses, as defined in Article 2(i). They shall make continuous efforts to enhance compliance with those essential features.

Article 5

Data transmission

1. Each Member State shall determine a reference date. The reference date shall fall in a year specified on the basis of this Regulation (reference year). The first reference year shall be 2011. The Commission (Eurostat) shall establish subsequent reference years in accordance with the regulatory procedure with scrutiny referred to in Article 8(3). Reference years shall fall during the beginning of every decade.

2. Member States shall provide the Commission (Eurostat) with final, validated and aggregated data and with metadata, as required by this Regulation, within 27 months of the end of the reference year.

3. The Commission (Eurostat) shall adopt a programme of the statistical data and of the metadata to be transmitted to fulfil the requirements of this Regulation, in accordance with the regulatory procedure with scrutiny referred to in Article 8(3).

4. The Commission (Eurostat) shall adopt the technical specifications of the topics as required by this Regulation as well as of their breakdowns, in accordance with the regulatory procedure referred to in Article 8(2).

5. Member States shall transmit to the Commission (Eurostat) the validated data and metadata in electronic form. The Commission (Eurostat) shall adopt the appropriate technical format to be used for the transmission of the required data, in accordance with the regulatory procedure referred to in Article 8(2).

6. In the event of a revision or correction in accordance with Article 4(3), Member States shall transmit the modified data to the Commission (Eurostat) no later than on the date of release of the revised data.

Article 6

Quality assessment

1. For the purpose of this Regulation, the following quality assessment dimensions shall apply to the data to be transmitted:

— 'relevance' shall refer to the degree to which statistics meet the current and potential needs of users,

— 'accuracy' shall refer to the closeness of estimates to the unknown true values,

— 'timeliness' and 'punctuality' shall refer to the delay between the reference period and the availability of results,

— 'accessibility' and 'clarity' shall refer to the conditions under and modalities by which users can obtain, use and interpret data,

— 'comparability' shall refer to the measurement of the impact of differences in applied statistical concepts and measurement tools and procedures when statistics are compared between geographical areas, sectoral domains, or over time, and

— 'coherence' shall refer to the adequacy of the data to be reliably combined in different ways and for various uses.

2. Member States shall provide the Commission (Eurostat) with a report on the quality of the data transmitted. In this context, Member States shall report on the extent to which the chosen data sources and methodology meet the essential features of population and housing censuses as defined in Article 2(i).

3. In applying the quality assessment dimensions laid down in paragraph 1 to the data covered by this Regulation, the modalities and structure of the quality reports shall be defined in accordance with the regulatory procedure referred to in Article 8(2). The Commission (Eurostat) shall assess the quality of the data transmitted.

4. The Commission (Eurostat), in cooperation with the competent authorities of the Member States, shall provide methodological recommendations designed to ensure the quality of the data and metadata produced, acknowledging, in particular, the Conference of European Statisticians Recommendations for the 2010 Censuses of Population and Housing.

Article 7

Implementing measures

1. The following measures necessary for the implementation of this Regulation shall be adopted in accordance with the regulatory procedure referred to in Article 8(2):

(a) technical specifications of the topics as required by this Regulation as well as of their breakdowns as provided for in Article 5(4);

(b) the establishment of the appropriate technical format as provided for in Article 5(5); and

(c) modalities and structure of the quality reports as provided for in Article 6(3).

2. The following measures necessary for the implementation of this Regulation, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 8(3):

(a) the establishment of the reference years, as provided for in Article 5(1); and

(b) the adoption of the programme of the statistical data and the metadata, as provided for in Article 5(3).

3. Consideration shall be given to the principles that the benefits of the measures taken must outweigh their costs and that additional costs and burdens must remain within a reasonable limit.

Article 8

Committee procedure

1. The Commission shall be assisted by the Statistical Programme Committee.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 9

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 9 July 2008.

For the European Parliament	*For the Council*
The President	*The President*
H.-G. PÖTTERING	J.-P. JOUYET

ANNEX

Topics to be covered in Population and Housing Censuses

1. Population topics

1.1. Obligatory topics for the geographical levels: NUTS 3, LAU 2

1.1.1. Non-derived topics

— Place of usual residence,

— sex,

— age,

— legal marital status,

— country/place of birth,

— country of citizenship,

— previous place of usual residence and date of arrival in the current place; or place of usual residence one year prior to the census,

— relationships between household members

1.1.2. Derived topics

— Total population,

— locality,

— household status,

— family status,

— type of family nucleus,

— size of family nucleus,

— type of private household,

— size of private household

1.2. Obligatory topics for the geographical levels: national level, NUTS 1, NUTS 2

1.2.1. Non-derived topics

— Place of usual residence,

— location of place of work,

— sex,

— age,

— legal marital status,

— current activity status,

— occupation,

— industry (branch of economic activity),

— status in employment,

— educational attainment,

— country/place of birth,

— country of citizenship,

— ever resided abroad and year of arrival in the country (from 1980),

— previous place of usual residence and date of arrival in the current place; or place of usual residence one year prior to the census,

— relationships between household members,

— tenure status of households

1.2.2. Derived topics

— Total population,

— locality,

— household status,

— family status,

— type of family nucleus,

— size of family nucleus,

— type of private household,

— size of private household

2. Housing topics

2.1. Obligatory topics for the geographical levels: NUTS 3, LAU 2

2.1.1. Non-derived topics

— Type of living quarters,

— location of living quarters,

— occupancy status of conventional dwellings,

— number of occupants,

— useful floor space and/or number of rooms of housing units,

— dwellings by type of building,

— dwellings by period of construction

2.1.2. Derived topics

— Density standard

2.2. Obligatory topics for the geographical levels: national level, NUTS 1, NUTS 2

2.2.1. Non-derived topics

— Housing arrangements,

— type of living quarters,

— location of living quarters,

— occupancy status of conventional dwellings,

— type of ownership,

— number of occupants,

— useful floor space and/or number of rooms of housing units,

— water supply system,

— toilet facilities,

— bathing facilities,

— type of heating,

— dwellings by type of building,

— dwellings by period of construction

2.2.2. Derived topics

— Density standard

REGULATION (EC) No 764/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 July 2008

laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37 and 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ([2]),

Whereas:

(1) The internal market comprises an area without internal frontiers, in which the free movement of goods is ensured under the Treaty, which prohibits measures having effects equivalent to quantitative restrictions on imports. That prohibition covers any national measure which is capable of hindering, directly or indirectly, actually or potentially, intra-Community trade in goods.

(2) Obstacles to the free movement of goods between Member States may be unlawfully created by the Member States' competent authorities applying, in the absence of harmonisation of legislation, to products lawfully marketed in other Member States, technical rules laying down requirements to be met by those products, such as rules relating to designation, form, size, weight, composition, presentation, labelling and packaging. The application of such rules to products lawfully marketed in another Member State can be contrary to Articles 28 and 30 of the Treaty, even if they apply without distinction to all products.

(3) The principle of mutual recognition, which derives from the case-law of the Court of Justice of the European Communities, is one of the means of ensuring the free movement of goods within the internal market. Mutual recognition applies to products which are not subject to Community harmonisation legislation, or to aspects of products falling outside the scope of such legislation. According to that principle, a Member State may not prohibit the sale on its territory of products which are lawfully marketed in another Member State, even where those products were manufactured in accordance with technical rules different from those to which domestic products are subject. The only exceptions to that principle are restrictions which are justified on the grounds set out in Article 30 of the Treaty, or on the basis of other overriding reasons of public interest and which are proportionate to the aim pursued.

(4) Many problems still exist as regards the correct application of the principle of mutual recognition by the Member States. It is therefore necessary to establish procedures to minimise the possibility of technical rules' creating unlawful obstacles to the free movement of goods between Member States. The absence of such procedures in the Member States creates additional obstacles to the free movement of goods, since it discourages enterprises from selling their products, lawfully marketed in another Member State, on the territory of the Member State applying technical rules. Surveys have shown that many enterprises, in particular small and medium-sized enterprises (SMEs), either adapt their products in order to comply with the technical rules of Member States, or refrain from marketing them in those Member States.

(5) Competent authorities also lack appropriate procedures for the application of their technical rules to specific products lawfully marketed in another Member State. The lack of such procedures compromises their ability to assess the conformity of products in accordance with the Treaty.

(6) The Council Resolution of 28 October 1999 on mutual recognition ([3]) noted that economic operators and citizens did not always make full and proper use of the principle of mutual recognition because they were not sufficiently

([1]) OJ C 120, 16.5.2008, p. 1.

([2]) Opinion of the European Parliament of 21 February 2008 (not yet published in the Official Journal) and Council Decision of 23 June 2008.

([3]) OJ C 141, 19.5.2000, p. 5.

aware of the principle and its operational consequences. It called upon the Member States to develop appropriate measures in order to provide economic operators and citizens with an effective framework for mutual recognition, *inter alia*, by dealing effectively with requests from economic operators and citizens and by replying rapidly to those requests.

(7) The European Council of 8 and 9 March 2007 underlined the importance of giving fresh impetus to the internal market in goods by strengthening mutual recognition, while guaranteeing a high level of safety and consumer protection. The European Council of 21 and 22 June 2007 stressed that the further strengthening of the four freedoms of the internal market (the free movement of goods, persons, services and capital) and improving its functioning remain of paramount importance for growth, competitiveness and employment.

(8) The smooth functioning of the internal market in goods requires adequate and transparent means of solving the problems that result from applying technical rules of a Member State to specific products lawfully marketed in another Member State.

(9) This Regulation should not prejudice further harmonisation of technical rules, where appropriate, with a view to improving the functioning of the internal market.

(10) Trade barriers may also result from other types of measures falling within the scope of Articles 28 and 30 of the Treaty. Those measures may, for example, include technical specifications drawn up for public procurement procedures or obligations to use official languages in the Member States. However, such measures should not constitute technical rules within the meaning of this Regulation and should not therefore fall within its scope.

(11) Technical rules within the meaning of this Regulation are sometimes applied during and by means of mandatory prior authorisation procedures, established by the law of a Member State and in accordance with which, before a product or type of product may be placed on that Member State's market or on a part thereof, the competent authority of that Member State should give its formal approval following an application. The existence of such procedures in itself restricts the free movement of goods. Therefore, in order to be justified with regard to the fundamental principle of the free movement of goods within the internal market, a mandatory prior authorisation procedure should pursue a public-interest objective recognised by Community law, and should be non-discriminatory and proportionate; that is to say, it should be appropriate to ensure achievement of the aim pursued but not go beyond what is necessary in order to achieve that aim. The compliance of such a procedure with the principle of proportionality should be assessed in the light of the considerations set out in the case-law of the Court of Justice.

(12) A requirement that the placing of a product on the market be subject to prior authorisation should, as such, not constitute a technical rule within the meaning of this Regulation, so that a decision to exclude or remove a product from the market exclusively on the grounds that it does not have valid prior authorisation should not constitute a decision to which this Regulation applies. When, however, an application for such mandatory prior authorisation of a product is made, any intended decision to reject the application on the basis of a technical rule should be taken in accordance with this Regulation, so that the applicant could benefit from the procedural protection which this Regulation provides.

(13) Decisions of national courts or tribunals assessing the legality of cases in which, on account of the application of a technical rule, products lawfully marketed in one Member State are not granted access to the market of another Member State, or applying penalties, should be excluded from the scope of this Regulation.

(14) Weapons are products that can constitute a serious risk to the health and safety of persons and to the public security of Member States. Several specific types of weapons lawfully marketed in one Member State might, on grounds of the protection of the health and safety of persons and the prevention of crime, be subject to restrictive measures in another Member State. Such measures might consist of specific controls and authorisations before weapons lawfully marketed in one Member State are placed on the market of another Member State. Member States should therefore be permitted to prevent weapons being placed on their markets until their national procedural requirements are fully met.

(15) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety [1] specifies that only safe products may be placed on the market and lays down the obligations of producers and distributors with respect to the safety of products. It entitles the authorities to ban any dangerous product with immediate effect or, for the period needed for the various safety evaluations, checks and controls, to ban temporarily a product that could be dangerous. It also entitles the authorities to take the necessary action to apply with due dispatch appropriate measures such as those referred to in Article 8(1)(b) to (f) thereof, in the case of products posing a serious risk. Therefore, measures taken by the competent authorities of the Member States pursuant to national laws adopted in implementation of Article 8(1)(d) to (f) and Article 8(3) of that Directive should be excluded from the scope of this Regulation.

[1] OJ L 11, 15.1.2002, p. 4.

(16) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ([1]) establishes, *inter alia*, a rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed. It obliges the Member States to notify the Commission immediately under the rapid alert system of any measure they adopt which is aimed at restricting the placing on the market of, withdrawing from the market or recalling food or feed in order to protect human health, and which requires rapid action. Measures taken by the competent authorities of the Member States pursuant to Article 50(3)(a) and Article 54 of that Regulation should therefore be excluded from the scope of this Regulation.

(17) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ([2]) lays down general rules for the performance of official controls to verify compliance with rules intended, in particular, to prevent, eliminate or reduce to acceptable levels risks to humans and animals, either directly or through the environment, guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information. It lays down a specific procedure to ensure that economic operators remedy a situation of non-compliance with feed and food law, animal health and animal welfare rules. Measures taken by the competent authorities of the Member States pursuant to Article 54 of that Regulation should therefore be excluded from the scope of this Regulation. However, measures taken or intended to be taken by competent authorities on the basis of national technical rules, insofar as they do not concern the objectives of Regulation (EC) No 882/2004, should be subject to this Regulation.

(18) Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways (Railway Safety Directive) ([3]) provides for a procedure for authorisation of the placing in service of existing rolling stock, leaving scope for the application of certain national rules. Measures taken by the competent authorities pursuant to Article 14 of that Directive should therefore be excluded from the scope of this Regulation.

(19) Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail system ([4]) and Directive 2001/16/EC of the European Parliament and of the Council of 19 March 2001 on the interoperability of the trans-European conventional rail system ([5]) provide for the gradual harmonisation of systems and operations through the progressive adoption of Technical Specifications for Interoperability. Systems and interoperability constituents that fall within the scope of those Directives should therefore be excluded from the scope of this Regulation.

(20) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products ([6]) establishes a system of accreditation which ensures the mutual acceptance of the level of competence of conformity-assessment bodies. The competent authorities of the Member States should therefore no longer refuse test reports and certificates issued by an accredited conformity-assessment body on grounds related to the competence of that body. Furthermore, Member States may also accept test reports and certificates issued by other conformity-assessment bodies in accordance with Community law.

(21) Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services ([7]) obliges Member States to communicate to the Commission and the other Member States any draft technical regulation concerning any product, including agricultural and fish products, and a statement of the grounds which make the enactment of that regulation necessary. It is necessary, however, to ensure that, following the adoption of such a technical regulation, the principle of mutual recognition is correctly applied in individual cases to specific products. This Regulation lays down a procedure for the application of the principle of mutual recognition in individual cases, by means of the obligation on the competent authority to indicate the technical or scientific grounds on which the specific product in its current form

([1]) OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 202/2008 (OJ L 60, 5.3.2008, p. 17).

([2]) OJ L 165, 30.4.2004; corrected version in OJ L 191, 28.5.2004, p. 1. Regulation as amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

([3]) OJ L 164, 30.4.2004, p. 44; corrected version in OJ L 220, 21.6.2004, p. 16.

([4]) OJ L 235, 17.9.1996, p. 6. Directive as last amended by Commission Directive 2007/32/EC (OJ L 141, 2.6.2007, p. 63).

([5]) OJ L 110, 20.4.2001, p. 1. Directive as last amended by Commission Directive 2007/32/EC.

([6]) See page 30 of this Official Journal.

([7]) OJ L 204, 21.7.1998, p. 37. Directive as last amended by Council Directive 2006/96/EC (OJ L 363, 20.12.2006, p. 81).

cannot be marketed in its Member State, in accordance with Articles 28 and 30 of the Treaty. In the context of this Regulation, evidence should not be understood as meaning legal proof. The authorities of the Member States are not obliged, in the context of this Regulation, to justify the technical rule itself. However, they should justify, as laid down in this Regulation, the possible application of the technical rule to a product lawfully marketed in another Member State.

(22) In accordance with the principle of mutual recognition, the procedure laid down in this Regulation should provide for the competent authorities to communicate in each case to the economic operator, on the basis of the relevant technical or scientific elements available, that there are overriding reasons of public interest for imposing national technical rules on the product or type of product in question and that less restrictive measures cannot be used. The written notice should allow the economic operator to comment on all relevant aspects of the intended decision restricting access to the market. Nothing prevents the competent authority from taking action after the deadline for the receipt of those comments in the absence of a reply from the economic operator.

(23) The concept of overriding reasons of public interest to which reference is made in certain provisions of this Regulation is an evolving concept developed by the Court of Justice in its case law in relation to Articles 28 and 30 of the Treaty. This concept covers, *inter alia*, the effectiveness of fiscal supervision, the fairness of commercial transactions, the protection of consumers, the protection of the environment, the maintenance of press diversity and the risk of seriously undermining the financial balance of the social security system. Such overriding reasons may justify the application of technical rules by the competent authorities. However, no such application should constitute a means of arbitrary discrimination or a disguised restriction of trade between Member States. Furthermore, the principle of proportionality should always be respected, regard being had to whether the competent authority has in fact made use of the least restrictive measure.

(24) While applying the procedure laid down in this Regulation, the competent authority of a Member State should not withdraw or restrict the placing on its market of a product or type of product lawfully marketed in another Member State. However, it is appropriate that a competent authority be able to adopt provisional measures where rapid intervention is required to prevent harm to safety and health of users. Such provisional measures may also be adopted by a competent authority to prevent the placing on its market of a product the marketing of which is generally prohibited on grounds of public morality or public security, including the prevention of crime. Therefore, Member States should be allowed, at any stage of the procedure laid down in this Regulation, to suspend temporarily the marketing on their territories of products or types of product under those circumstances.

(25) Any decision to which this Regulation applies should specify the remedies available so that an economic operator can bring proceedings before the competent national court or tribunal.

(26) It is appropriate that the economic operator also be informed of the availability of non-judicial problem-solving mechanisms, such as the SOLVIT system, in order to prevent legal uncertainty and legal costs.

(27) Once a competent authority has taken a decision to exclude a product on the basis of a technical rule in accordance with the procedural requirements of this Regulation, no further action taken in relation to that product which is based on that decision and on the same technical rule should be subject to the requirements of this Regulation.

(28) It is important for the internal market in goods that the accessibility of national technical rules be ensured, so that enterprises, and in particular SMEs, can gather reliable and precise information concerning the law in force.

(29) It is therefore necessary to implement principles of administrative simplification, *inter alia*, through the establishment of a system of Product Contact Points. This should be designed to ensure that enterprises can gain access to information in a transparent and correct manner, so that the delays, costs and dissuasive effects which result from national technical rules can be prevented.

(30) In order to facilitate the free movement of goods, Product Contact Points should provide, free of charge, information concerning their national technical rules and the application of the principle of mutual recognition as regards products. Product Contact Points should be adequately equipped and resourced and encouraged also to make the information available through a website and in other Community languages. Product Contact Points could also provide economic operators with additional information or observations during the procedure laid down in this Regulation. For additional information, Product Contact Points may charge fees that are proportionate to the costs of this information.

(31) Since the creation of Product Contact Points should not interfere with the allocation of functions among competent authorities within the regulatory systems of the Member States, it should be possible for Member States to set up Product Contact Points according to regional or local

competences. Member States should be able to entrust the role of Product Contact Points to existing contact points established in accordance with other Community instruments, in order to prevent the unnecessary proliferation of contact points and to simplify administrative procedures. Member States should also be able to entrust the role of Product Contact Points not only to existing services within the public administration, but also to national SOLVIT centres, chambers of commerce, professional organisations and private bodies, in order not to increase administrative costs for enterprises and competent authorities.

(32) Member States and the Commission should be encouraged to work closely together to facilitate the training of staff employed in Product Contact Points.

(33) In view of the development and establishment of a pan-European eGovernment service and the underlying interoperable telematic networks, the possibility of establishing an electronic system for the exchange of information between Product Contact Points should be envisaged, in accordance with Decision 2004/387/EC of the European Parliament and of the Council of 21 April 2004 on the interoperable delivery of pan-European eGovernment services to public administrations, businesses and citizens (IDABC) ([1]).

(34) Reliable and efficient monitoring and evaluation mechanisms should be established in order to provide information on the application of this Regulation so as to enhance knowledge concerning the functioning of the internal market in goods in sectors not subject to harmonisation and to ensure that the principle of mutual recognition is duly applied by the competent authorities of the Member States. Such mechanisms should not go beyond what is necessary to achieve those objectives.

(35) This Regulation applies only to products or particular features of products which are not subject to Community harmonisation measures intended to eliminate obstacles to trade between Member States resulting from the existence of divergent national technical rules. The provisions of such harmonisation measures are often exhaustive, in which case Member States may not prohibit, restrict or impede the placing on the market in their territories of products complying with those measures. Some Community harmonisation measures, however, permit Member States to impose additional technical conditions on the placing of a product on their market. Such additional conditions should be subject to Articles 28 and 30 of the Treaty and to the provisions of this Regulation. It is therefore appropriate, with a view to the efficient application of this Regulation, that the Commission should establish an indicative and non-exhaustive list of products which are not subject to harmonisation at Community level.

(36) The monitoring scheme established by Decision No 3052/95/EC of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community ([2]) has proved largely unsuccessful in that its implementation has not provided the Commission with sufficient information to identify sectors where harmonisation might be appropriate. Nor has it brought about a rapid resolution of certain free-movement problems. Decision No 3052/95/EC should therefore be repealed.

(37) It is appropriate to introduce a transitional period for the application of this Regulation, in order to enable the competent authorities to adapt to the requirements laid down herein.

(38) Since the objective of this Regulation, namely the elimination of technical obstacles to the free movement of goods between Member States, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(39) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([3]),

HAVE ADOPTED THIS REGULATION:

CHAPTER 1

SUBJECT MATTER AND SCOPE

Article 1

Subject matter

1. The aim of this Regulation is to strengthen the functioning of the internal market by improving the free movement of goods.

2. This Regulation lays down the rules and procedures to be followed by the competent authorities of a Member State when taking or intending to take a decision, as referred to in Article 2(1), which would hinder the free movement of a product lawfully marketed in another Member State and subject to Article 28 of the Treaty.

([1]) OJ L 144, 30.4.2004; corrected version in OJ L 181, 18.5.2004, p. 25.

([2]) OJ L 321, 30.12.1995, p. 1.

([3]) OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

3. It also provides for the establishment of Product Contact Points in the Member States to contribute to the achievement of the aim of this Regulation, as set out in paragraph 1.

Article 2

Scope

1. This Regulation shall apply to administrative decisions addressed to economic operators, whether taken or intended, on the basis of a technical rule as defined in paragraph 2, in respect of any product, including agricultural and fish products, lawfully marketed in another Member State, where the direct or indirect effect of that decision is any of the following:

(a) the prohibition of the placing on the market of that product or type of product;

(b) the modification or additional testing of that product or type of product before it can be placed or kept on the market;

(c) the withdrawal of that product or type of product from the market.

For the purposes of point (b) of the first subparagraph, modification of the product or type of product shall mean any modification of one or more of the characteristics of a product or a type of product as listed in point (b)(i) of paragraph 2.

2. For the purposes of this Regulation, a technical rule is any provision of a law, regulation or other administrative provision of a Member State:

(a) which is not the subject of harmonisation at Community level; and

(b) which prohibits the marketing of a product or type of product in the territory of that Member State or compliance with which is compulsory when a product or type of product is marketed in the territory of that Member State, and which lays down either:

(i) the characteristics required of that product or type of product, such as levels of quality, performance or safety, or dimensions, including the requirements applicable to the product or product type as regards the name under which it is sold, terminology, symbols, testing and test methods, packaging, marking or labelling; or

(ii) any other requirement which is imposed on the product or type of product for the purposes of protecting consumers or the environment, and which affects the life-cycle of the product after it has been placed on the market, such as conditions of use, recycling, reuse or disposal, where such conditions can significantly influence the composition, nature or marketing of the product or type of product.

3. This Regulation shall not apply to:

(a) decisions of a judicial nature taken by national courts or tribunals;

(b) decisions of a judicial nature taken by law enforcement authorities in the course of the investigation or prosecution of a criminal offence as regards the terminology, symbols or any material reference to unconstitutional or criminal organisations or offences of a racist or xenophobic nature.

Article 3

Relationship with other provisions of Community law

1. This Regulation shall not apply to systems or interoperability constituents falling within the scope of Directives 96/48/EC and 2001/16/EC.

2. This Regulation shall not apply in the case of measures taken by the authorities of the Member States pursuant to:

(a) Article 8(1)(d) to (f) and Article 8(3) of Directive 2001/95/EC;

(b) Article 50(3)(a) and Article 54 of Regulation (EC) No 178/2002;

(c) Article 54 of Regulation (EC) No 882/2004;

(d) Article 14 of Directive 2004/49/EC.

CHAPTER 2

PROCEDURE FOR THE APPLICATION OF A TECHNICAL RULE

Article 4

Information on the product

Where a competent authority submits a product or type of product to an evaluation to determine whether or not to adopt a decision as referred to in Article 2(1), it may request from the economic operator identified in accordance with Article 8, with due regard to the principle of proportionality, any of the following in particular:

(a) relevant information concerning the characteristics of the product or type of product in question;

(b) relevant and readily available information on the lawful marketing of the product in another Member State.

Article 5

Mutual recognition of the level of competence of accredited conformity-assessment bodies

Member States shall not refuse certificates or test reports issued by a conformity-assessment body accredited for the appropriate field of conformity-assessment activity in accordance with Regulation (EC) No 765/2008 on grounds related to the competence of that body.

Article 6

Assessment of the need to apply a technical rule

1. Where a competent authority intends to adopt a decision as referred to in Article 2(1), it shall send the economic operator identified in accordance with Article 8 written notice of that intention, specifying the technical rule on which the decision is to be based and setting out technical or scientific evidence to the effect that:

(a) the intended decision is justified on one of the grounds of public interest set out in Article 30 of the Treaty or by reference to other overriding reasons of public interest; and

(b) the intended decision is appropriate for the purpose of achieving the objective pursued and does not go beyond what is necessary in order to attain that objective.

Any intended decision shall be based on the characteristics of the product or type of product in question.

The economic operator concerned shall, following receipt of such notice, be allowed at least 20 working days in which to submit comments. The notice shall specify the time limit within which comments may be submitted.

2. Any decision as referred to in Article 2(1) shall be taken and notified to the economic operator concerned and to the Commission within a period of 20 working days from the expiry of the time limit for the receipt of comments from the economic operator referred to in paragraph 1 of this Article. It shall take due account of those comments and shall state the grounds on which it is based, including the reasons for rejecting the arguments, if any, put forward by the operator, and the technical or scientific evidence as referred to in paragraph 1 of this Article.

Where duly justified by the complexity of the issue, the competent authority may, once only, extend the period specified in the first subparagraph by a maximum of 20 working days. That extension shall be duly reasoned and shall be notified to the economic operator before the expiry of the initial period.

Any decision as referred to in Article 2(1) shall also specify the remedies available under the law in force in the Member State concerned and the time limits applying to such remedies. Such a decision may be challenged before national courts or tribunals or other instances of appeal.

3. Where, after giving written notice in accordance with paragraph 1, the competent authority decides not to adopt a decision as referred to in Article 2(1), it shall immediately inform the economic operator concerned accordingly.

4. When the competent authority fails to notify the economic operator of a decision as referred to in Article 2(1) within the period specified in paragraph 2 of this Article, the product shall be deemed to be lawfully marketed in that Member State insofar as the application of its technical rule as referred to in paragraph 1 of this Article is concerned.

Article 7

Temporary suspension of the marketing of a product

1. The competent authority shall not temporarily suspend the marketing of the product or type of product in question, during the procedure laid down in this Chapter, except where either:

(a) under normal or reasonably foreseeable conditions of use, the product or type of product in question poses a serious risk to the safety and health of the users; or

(b) the marketing of the product or type of product in question is generally prohibited in a Member State on grounds of public morality or public security.

2. The competent authority shall immediately notify the economic operator identified in accordance with Article 8 and the Commission of any suspension as referred to in paragraph 1 of this Article. In the cases referred to in paragraph 1(a) of this Article, that notification shall be accompanied by a technical or scientific justification.

3. Any suspension of the marketing of a product pursuant to this Article may be challenged before national courts or tribunals or other instances of appeal.

Article 8

Information to the economic operator

References to the economic operators in Articles 4, 6 and 7 shall be considered references:

(a) to the manufacturer of the product, if established in the Community, or the person who has placed the product on the market or requests to the competent authority that the product be placed on the market;

(b) where the competent authority cannot establish the identity and contact details of any of the economic operators referred to in point (a), to the manufacturer's representative, when the manufacturer is not established in the Community or, if there is no representative established in the Community, to the importer of the product;

(c) where the competent authority cannot establish the identity and contact details of any of the economic operators referred to in points (a) and (b), to any professional in the supply chain whose activity may affect any property of the product regulated by the technical rule which is being applied to it;

(d) where the competent authority cannot establish the identity and contact details of any of the economic operators referred to in points (a), (b) and (c), to any professional in the supply chain whose activity does not affect any property of the product regulated by the technical rule which is being applied to it.

CHAPTER 3

PRODUCT CONTACT POINTS

Article 9

Establishment of Product Contact Points

1. Member States shall designate Product Contact Points in their territories and shall communicate their contact details to the other Member States and to the Commission.

2. The Commission shall draw up and regularly update a list of Product Contact Points and publish it in the *Official Journal of the European Union*. The Commission shall also make that information available through a website.

Article 10

Tasks

1. Product Contact Points shall, at the request of, *inter alia*, an economic operator or a competent authority of another Member State, provide the following information:

(a) the technical rules applicable to a specific type of product in the territory in which those Product Contact Points are established and information as to whether that type of product is subject to a requirement for prior authorisation under the laws of their Member State, together with information concerning the principle of mutual recognition and the application of this Regulation in the territory of that Member State;

(b) the contact details of the competent authorities within that Member State by means of which they may be contacted directly, including the particulars of the authorities responsible for supervising the implementation of the technical rules in question in the territory of that Member State;

(c) the remedies generally available in the territory of that Member State in the event of a dispute between the competent authorities and an economic operator.

2. Product Contact Points shall respond within 15 working days of receiving any request as referred to in paragraph 1.

3. Product Contact Points in the Member State in which the economic operator concerned has lawfully marketed the product in question may provide the economic operator or the competent authority as referred to in Article 6 with any relevant information or observations.

4. Product Contact Points shall not charge any fee for the provision of the information referred to in paragraph 1.

Article 11

Telematic network

The Commission may, in accordance with the advisory procedure referred to in Article 13(2), establish a telematic network for the implementation of the provisions of this Regulation concerning the exchange of information between Product Contact Points and/or the competent authorities of the Member States.

CHAPTER 4

FINAL PROVISIONS

Article 12

Reporting obligations

1. Each Member State shall send the Commission on a yearly basis a report on the application of this Regulation. That report shall include the following information at least:

(a) the number of written notices sent pursuant to Article 6(1) and the type of products concerned;

(b) sufficient information concerning any decisions taken pursuant to Article 6(2), including the grounds on which those decisions were based and the type of products concerned;

(c) the number of decisions taken pursuant to Article 6(3) and the type of products concerned.

2. In the light of the information provided by Member States pursuant to paragraph 1, the Commission shall analyse the decisions taken pursuant to Article 6(2) and assess the grounds on which they were based.

3. By 13 May 2012, and every five years thereafter, the Commission shall review the application of this Regulation and shall submit a report thereon to the European Parliament and to the Council. The Commission may, where appropriate, accompany the report with proposals with a view to improving the free movement of goods.

4. The Commission shall draw up, publish and regularly update a non-exhaustive list of products which are not subject to Community harmonisation legislation. It shall make that list accessible through a website.

Article 13

Committee procedure

1. The Commission shall be assisted by a committee composed of representatives of the Member States and chaired by a representative of the Commission.

2. Where reference is made to this paragraph, the advisory procedure laid down in Article 3 of Decision 1999/468/EC shall apply, in accordance with Article 7(3) and Article 8 thereof.

Article 14

Repeal

Decision No 3052/95/EC is hereby repealed with effect from 13 May 2009.

Article 15

Entry into force and application

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 13 May 2009.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 9 July 2008.

For the European Parliament	*For the Council*
The President	*The President*
H.-G. PÖTTERING	J.-P. JOUYET

REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 July 2008

setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 133 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ([2]),

Whereas:

(1) It is necessary to ensure that products benefiting from the free movement of goods within the Community fulfil requirements providing a high level of protection of public interests such as health and safety in general, health and safety at the workplace, protection of consumers, protection of the environment and security, while ensuring that the free movement of products is not restricted to any extent greater than that which is allowed under Community harmonisation legislation or any other relevant Community rules. Provision should, therefore, be made for rules on accreditation, market surveillance, controls of products from third countries and the CE marking.

(2) It is necessary to establish an overall framework of rules and principles in relation to accreditation and market surveillance. That framework should not affect the substantive rules of existing legislation setting out the provisions to be observed for the purpose of protecting public interests such as health, safety and protection of consumers and of the environment, but should aim at enhancing their operation.

(3) This Regulation should be seen as complementary to Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products ([3]).

(4) It is very difficult to adopt Community legislation for every product which exists or which may be developed; there is a need for a broad-based, legislative framework of a horizontal nature to deal with such products, to cover lacunae, in particular pending revision of existing specific legislation, and to complement provisions in existing or future specific legislation, in particular with a view to ensuring a high level of protection of health, safety, the environment and consumers, as required by Article 95 of the Treaty.

(5) The framework for market surveillance established by this Regulation should complement and strengthen existing provisions in Community harmonisation legislation relating to market surveillance and the enforcement of such provisions. However, in accordance with the principle of *lex specialis*, this Regulation should apply only in so far as there are no specific provisions with the same objective, nature or effect in other existing or future rules of Community harmonisation legislation. Examples can be found in the following sectors: drug precursors, medical devices, medicinal products for human and veterinary use, motor vehicles and aviation. The corresponding provisions of this Regulation should not therefore apply in the areas covered by such specific provisions.

(6) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety ([4]) established rules to ensure the safety of consumer products. Market surveillance authorities should have the possibility of taking the more specific measures available to them under that Directive.

(7) However, in order to achieve a higher level of safety for consumer products, the market surveillance mechanisms provided for in Directive 2001/95/EC should be reinforced as regards products presenting a serious risk, in accordance with the principles established by this Regulation. Directive 2001/95/EC should therefore be amended accordingly.

([1]) OJ C 120, 16.5.2008, p. 1.

([2]) Opinion of the European Parliament of 21 February 2008 (not yet published in the Official Journal) and Council Decision of 23 June 2008.

([3]) See page 82 of this Official Journal.

([4]) OJ L 11, 15.1.2002, p. 4.

(8) Accreditation is part of an overall system, including conformity assessment and market surveillance, designed to assess and ensure conformity with the applicable requirements.

(9) The particular value of accreditation lies in the fact that it provides an authoritative statement of the technical competence of bodies whose task is to ensure conformity with the applicable requirements.

(10) Accreditation, though so far not regulated at Community level, is carried out in all Member States. The lack of common rules for that activity has resulted in different approaches and differing systems throughout the Community, with the result that the degree of rigour applied in the performance of accreditation has varied between Member States. It is therefore necessary to develop a comprehensive framework for accreditation and to lay down at Community level the principles for its operation and organisation.

(11) The establishment of a uniform national accreditation body should be without prejudice to the allocation of functions within Member States.

(12) Where Community harmonisation legislation provides for the selection of conformity assessment bodies for its implementation, transparent accreditation, as provided for in this Regulation, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Community the preferred means of demonstrating the technical competence of those bodies. However, national authorities may consider that they possess the appropriate means of carrying out this evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

(13) A system of accreditation which functions by reference to binding rules helps to strengthen mutual confidence between Member States as regards the competence of conformity assessment bodies and consequently the certificates and test reports issued by them. It thereby enhances the principle of mutual recognition and therefore the provisions of this Regulation on accreditation should apply in relation to bodies carrying out conformity assessments in both the regulated and the non-regulated areas. The issue at stake is the quality of certificates and test reports irrespective of whether they fall within the regulated or the non-regulated area, and no distinction should therefore be made between those areas.

(14) For the purposes of this Regulation, not-for-profit operation by a national accreditation body should be understood as an activity that is not intended to add any gain to the resources of the body's owners or members. While national accreditation bodies do not have the objective of maximising or distributing profits, they may provide services in return for payment, or receive income. Any excess revenue that results from such services may be used for investment to develop their activities further, as long as it is in line with their main activities. It should accordingly be emphasised that the primary objective of national accreditation bodies should be to support or engage actively in activities that are not intended to produce any gain.

(15) Since the purpose of accreditation is to provide an authoritative statement of the competence of a body to perform conformity assessment activities, Member States should not maintain more than one national accreditation body and should ensure that that body is organised in such a way as to safeguard the objectivity and impartiality of its activities. Such national accreditation bodies should operate independently of commercial conformity assessment activities. It is therefore appropriate to provide that Member States ensure that, in the performance of their tasks, national accreditation bodies are deemed to exercise public authority, irrespective of their legal status.

(16) For the assessment and continued monitoring of the competence of a conformity assessment body, it is essential to determine its technological knowledge and experience and its ability to carry out assessment. It is therefore necessary that the national accreditation body possess the relevant knowledge, competence and means for the proper performance of its tasks.

(17) Accreditation should in principle be operated as a self-supporting activity. Member States should ensure that financial support exists for the fulfilment of special tasks.

(18) In those cases where it is not economically meaningful or sustainable for a Member State to establish a national accreditation body, that Member State should have recourse to the national accreditation body of another Member State and should be encouraged to have such recourse to the fullest extent possible.

(19) Competition between national accreditation bodies could lead to the commercialisation of their activity, which would be incompatible with their role as the last level of control in the conformity assessment chain. The objective of this Regulation is to ensure that, within the European Union, one accreditation certificate is sufficient for the whole territory of the Union, and to avoid multiple accreditation, which is added cost without added value. National accreditation bodies may find themselves in competition on the markets of third countries, but that must have no effect on their activities inside the Community, or on the cooperation and peer evaluation activities organised by the body recognised under this Regulation.

(20) In order to avoid multiple accreditation, to enhance acceptance and recognition of accreditation certificates and to carry out effective monitoring of accredited conformity assessment bodies, conformity assessment bodies should request accreditation by the national accreditation body of the Member State in which they are established. Nevertheless, it is necessary to ensure that a conformity assessment body is able to request accreditation in another Member State in the event that there is no national accreditation body in its own Member State or where the national accreditation body is not competent to provide the accreditation services requested. In such cases, appropriate cooperation and exchange of information between national accreditation bodies should be established.

(21) In order to ensure that national accreditation bodies fulfil the requirements and obligations provided for in this Regulation, it is important that Member States support the proper functioning of the accreditation system, monitor their national accreditation bodies regularly and take appropriate corrective measures within a reasonable timeframe where necessary.

(22) In order to ensure the equivalence of the level of competence of conformity assessment bodies, to facilitate mutual recognition and to promote the overall acceptance of accreditation certificates and conformity assessment results issued by accredited bodies, it is necessary that national accreditation bodies operate a rigorous and transparent peer evaluation system and regularly undergo such evaluation.

(23) This Regulation should provide for the recognition of a single organisation at European level in respect of certain functions in the field of accreditation. The European cooperation for Accreditation (the EA), whose main mission is to promote a transparent and quality-led system for the evaluation of the competence of conformity assessment bodies throughout Europe, manages a peer evaluation system among national accreditation bodies from the Member States and other European countries. That system has proved to be efficient and to provide mutual confidence. The EA should, therefore, be the first body recognised under this Regulation and Member States should ensure that their national accreditation bodies seek and maintain membership of the EA for as long as it is so recognised. At the same time, the possibility of changing the relevant body recognised under this Regulation should be provided for, in case there is a need for it in the future.

(24) Effective cooperation among national accreditation bodies is essential for the proper implementation of peer evaluation and with regard to cross-border accreditation. In the interests of transparency, it is, therefore, necessary to provide for an obligation on national accreditation bodies to exchange information among themselves and to provide the national authorities and the Commission with relevant information. Updated and accurate information concerning the availability of accreditation activities operated by national accreditation bodies should also be made public and, therefore, accessible, in particular to conformity assessment bodies.

(25) Sectoral accreditation schemes should cover the fields of activity where general requirements for the competence of conformity assessment bodies are not sufficient to ensure the necessary level of protection where specific detailed technology or health and safety-related requirements are imposed. Given the fact that the EA has at its disposal a broad range of technical expertise, it should be requested to develop such schemes, especially for areas covered by Community legislation.

(26) For the purpose of ensuring the equivalent and consistent enforcement of Community harmonisation legislation, this Regulation introduces a Community market surveillance framework, defining minimum requirements against the background of the objectives to be achieved by Member States and a framework for administrative cooperation including the exchange of information among Member States.

(27) In the case of economic operators in possession of test reports or certificates attesting conformity issued by an accredited conformity assessment body, where the relevant Community harmonisation legislation does not require such reports or certificates, market surveillance authorities should take due account of them when performing checks on product characteristics.

(28) Cooperation between competent authorities at national level and across borders in exchanging information, investigating infringements and taking action to bring about their cessation, even before the placing on the market of dangerous products, by reinforcing measures to identify them, mainly in seaports, is essential to the protection of health and safety and to guaranteeing the smooth functioning of the internal market. National consumer protection authorities should cooperate, at national level, with national market surveillance authorities and should exchange information with them relating to products which they suspect present a risk.

(29) Risk assessment should take all relevant data into account, including, where available, data on risks that have materialised with respect to the product in question. Account should also be taken of any measures that may have been taken by the economic operators concerned to alleviate the risks.

(30) Situations of serious risk posed by a product require rapid intervention, which may entail the withdrawal of the product, its recall or the prohibition of its being made available on the market. In those situations it is necessary to have access to a system of rapid exchange of information between Member States and the Commission. The system

provided for in Article 12 of Directive 2001/95/EC has proved its effectiveness and efficiency in the field of consumer products. To avoid unnecessary duplication, that system should be used for the purposes of this Regulation. Moreover, coherent market surveillance throughout the Community requires a comprehensive exchange of information on national activities in this context which goes beyond this system.

(31) Information exchanged between competent authorities should be subject to the strictest guarantees of confidentiality and professional secrecy and be handled in accordance with rules on confidentiality pursuant to the applicable national law or, as regards the Commission, Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents ([1]), in order to ensure that investigations are not compromised and that the reputations of economic operators are not prejudiced. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ([2]) and Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data ([3]) apply in the context of this Regulation.

(32) Community harmonisation legislation provides for specific procedures establishing whether or not a national measure restricting the free movement of a product is justified (safeguard clause procedures). Those procedures apply following a rapid exchange of information on products presenting a serious risk.

(33) Points of entry at the external borders are well placed to detect unsafe non-conforming products or products to which the CE marking has been affixed falsely or in a misleading manner even before they are placed on the market. An obligation on authorities in charge of the control of products entering the Community market to execute checks on an adequate scale can therefore contribute to a safer market place. In order to increase the effectiveness of such checks, those authorities should receive all the necessary information concerning dangerous non-conforming products from the market surveillance authorities well in advance.

(34) Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries ([4]) lays down rules regarding the suspension of the release of products by customs authorities and provides for further measures including the involvement of market surveillance authorities. It is therefore appropriate that those provisions, including the involvement of market surveillance authorities, be incorporated in this Regulation.

(35) Experience has shown that products which are not released are often re-exported and subsequently enter the Community market at other points of entry, thus undermining the customs authorities' efforts. Market surveillance authorities should therefore be given the means of proceeding with the destruction of products if they deem it appropriate.

(36) Within one year of the publication of this Regulation in the *Official Journal of the European Union*, the Commission should present an in-depth analysis in the realm of consumer safety markings, followed by legislative proposals where necessary.

(37) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking should be set out in this Regulation so as to make them immediately applicable and to simplify future legislation.

(38) The CE marking should be the only marking of conformity indicating that a product is in conformity with Community harmonisation legislation. However, other markings may be used as long as they contribute to the improvement of consumer protection and are not covered by Community harmonisation legislation.

(39) It is necessary for Member States to provide for appropriate means of redress in the competent courts and tribunals in respect of measures taken by the competent authorities which restrict the placing on the market of a product or which require its withdrawal or recall.

(40) Member States may find it useful to establish cooperation with the stakeholders concerned, including sectoral professional organisations and consumer organisations, in order to take advantage of available market intelligence when establishing, implementing and updating market surveillance programmes.

(41) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those

([1]) OJ L 145, 31.5.2001, p. 43.

([2]) OJ L 281, 23.11.1995, p. 31. Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

([3]) OJ L 8, 12.1.2001, p. 1.

([4]) OJ L 40, 17.2.1993, p. 1. Regulation as last amended by Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

penalties should be effective, proportionate and dissuasive and could be increased if the relevant economic operator has previously committed a similar infringement of the provisions of this Regulation.

(42) In order to achieve the objectives of this Regulation, it is necessary for the Community to contribute to the financing of activities required to implement policies in the field of accreditation and market surveillance. Financing should be provided in the form of grants to the body recognised under this Regulation without a call for proposals, in the form of grants after a call for proposals, or by the award of contracts to that or to other bodies, depending on the nature of the activity to be financed and in accordance with Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities [1] (the Financial Regulation).

(43) For some specialised tasks, such as the production and revision of sectoral accreditation schemes, and for other tasks related to the verification of the technical competence and the facilities of laboratories and certification or inspection bodies, the EA should initially be eligible for Community financing, since it is well adapted to providing the necessary technical expertise in this respect.

(44) Given the role of the body recognised under this Regulation in the peer evaluation of accreditation bodies and its ability to assist the Member States with the management of that peer evaluation, the Commission should be in a position to provide grants for the functioning of the secretariat of the body recognised under this Regulation, which should provide ongoing support for accreditation activities at Community level.

(45) A partnership agreement should be signed, in accordance with the provisions of the Financial Regulation, between the Commission and the body recognised under this Regulation in order to fix the administrative and financial rules on the financing of accreditation activities.

(46) In addition, financing should also be available to bodies other than the body recognised under this Regulation for other activities in the field of conformity assessment, metrology, accreditation and market surveillance, such as the drawing-up and updating of guidelines, inter-comparison activities linked to the operation of safeguard clauses, preliminary or ancillary activities in connection with the implementation of Community legislation in those areas and programmes of technical assistance and cooperation with third countries as well as the enhancement of policies in those areas at Community and international level.

(47) This Regulation respects the fundamental rights and observes the principles reflected in the Charter of Fundamental Rights of the European Union.

(48) Since the objective of this Regulation, namely to ensure that products on the market covered by Community legislation fulfil requirements providing a high level of protection of health and safety and other public interests while guaranteeing the functioning of the internal market by providing a framework for accreditation and market surveillance, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing conformity assessment activities.

2. This Regulation provides a framework for the market surveillance of products to ensure that those products fulfil requirements providing a high level of protection of public interests, such as health and safety in general, health and safety at the workplace, the protection of consumers, protection of the environment and security.

3. This Regulation provides a framework for controls on products from third countries.

4. This Regulation lays down the general principles of the CE marking.

Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

1. 'making available on the market' shall mean any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;

[1] OJ L 248, 16.9.2002, p. 1. Regulation as last amended by Regulation (EC) No 1525/2007 (OJ L 343, 27.12.2007, p. 9).

2. 'placing on the market' shall mean the first making available of a product on the Community market;

3. 'manufacturer' shall mean any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark;

4. 'authorised representative' shall mean any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under the relevant Community legislation;

5. 'importer' shall mean any natural or legal person established within the Community who places a product from a third country on the Community market;

6. 'distributor' shall mean any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;

7. 'economic operators' shall mean the manufacturer, the authorised representative, the importer and the distributor;

8. 'technical specification' shall mean a document that prescribes technical requirements to be fulfilled by a product, process or service;

9. 'harmonised standard' shall mean a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services ([1]) on the basis of a request made by the Commission in accordance with Article 6 of that Directive;

10. 'accreditation' shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity;

11. 'national accreditation body' shall mean the sole body in a Member State that performs accreditation with authority derived from the State;

12. 'conformity assessment' shall mean the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled;

13. 'conformity assessment body' shall mean a body that performs conformity assessment activities including calibration, testing, certification and inspection;

14. 'recall' shall mean any measure aimed at achieving the return of a product that has already been made available to the end user;

15. 'withdrawal' shall mean any measure aimed at preventing a product in the supply chain from being made available on the market;

16. 'peer evaluation' shall mean a process for the assessment of a national accreditation body by other national accreditation bodies, carried out in accordance with the requirements of this Regulation, and, where applicable, additional sectoral technical specifications;

17. 'market surveillance' shall mean the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Community harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;

18. 'market surveillance authority' shall mean an authority of a Member State responsible for carrying out market surveillance on its territory;

19. 'release for free circulation' shall mean the procedure laid down in Article 79 of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code ([2]);

20. 'CE marking' shall mean a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing;

21. 'Community harmonisation legislation' shall mean any Community legislation harmonising the conditions for the marketing of products.

CHAPTER II

ACCREDITATION

Article 3

Scope

This Chapter shall apply to accreditation, used on a compulsory or voluntary basis, relating to conformity assessment, whether that assessment is compulsory or not, and irrespective of the legal status of the body performing the accreditation.

([1]) OJ L 204, 21.7.1998, p. 37. Directive as last amended by Council Directive 2006/96/EC (OJ L 363, 20.12.2006, p. 81).

([2]) OJ L 302, 19.10.1992, p. 1. Regulation as last amended by Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

Article 4

General principles

1. Each Member State shall appoint a single national accreditation body.

2. Where a Member State considers that it is not economically meaningful or sustainable to have a national accreditation body or to provide certain accreditation services, it shall, as far as possible, have recourse to the national accreditation body of another Member State.

3. A Member State shall inform the Commission and the other Member States where, in accordance with paragraph 2, recourse is had to the national accreditation body of another Member State.

4. On the basis of the information referred to in paragraph 3 and Article 12, the Commission shall draw up and update a list of national accreditation bodies which it shall make publicly available.

5. Where accreditation is not operated directly by the public authorities themselves, a Member State shall entrust its national accreditation body with the operation of accreditation as a public authority activity and grant it formal recognition.

6. The responsibilities and tasks of the national accreditation body shall be clearly distinguished from those of other national authorities.

7. The national accreditation body shall operate on a not-for-profit basis.

8. The national accreditation body shall not offer or provide any activities or services that conformity assessment bodies provide, nor shall it provide consultancy services, own shares in or otherwise have a financial or managerial interest in a conformity assessment body.

9. Each Member State shall ensure that its national accreditation body has the appropriate financial and personnel resources for the proper performance of its tasks, including the fulfilment of special tasks, such as activities for European and international accreditation cooperation and activities that are required to support public policy and which are not self-financing.

10. The national accreditation body shall be a member of the body recognised under Article 14.

11. National accreditation bodies shall establish and maintain appropriate structures to ensure the effective and balanced involvement of all interested parties within both their organisations and the body recognised under Article 14.

Article 5

Operation of accreditation

1. A national accreditation body shall, when requested by a conformity assessment body, evaluate whether that conformity assessment body is competent to carry out a specific conformity assessment activity. Where it is found to be competent, the national accreditation body shall issue an accreditation certificate to that effect.

2. When a Member State decides not to use accreditation, it shall provide the Commission and the other Member States with all the documentary evidence necessary for the verification of the competence of the conformity assessment bodies it selects for the implementation of the Community harmonisation legislation in question.

3. National accreditation bodies shall monitor the conformity assessment bodies to which they have issued an accreditation certificate.

4. Where a national accreditation body ascertains that a conformity assessment body which has received an accreditation certificate is no longer competent to carry out a specific conformity assessment activity or has committed a serious breach of its obligations, that accreditation body shall take all appropriate measures within a reasonable timeframe to restrict, suspend or withdraw the accreditation certificate.

5. Member States shall establish procedures for the resolution of appeals, including, where appropriate, legal remedies against accreditation decisions or the absence thereof.

Article 6

Principle of non-competition

1. National accreditation bodies shall not compete with conformity assessment bodies.

2. National accreditation bodies shall not compete with other national accreditation bodies.

3. National accreditation bodies shall be permitted to operate across national borders, within the territory of another Member State, either at the request of a conformity assessment body in the circumstances set out in Article 7(1), or, if they are asked to do so by a national accreditation body in accordance with Article 7(3), in cooperation with the national accreditation body of that Member State.

Article 7

Cross-border accreditation

1. Where a conformity assessment body requests accreditation it shall do so with the national accreditation body of the Member State in which it is established or with the national accreditation body to which that Member State has had recourse in accordance with Article 4(2).

However, a conformity assessment body may request accreditation by a national accreditation body other than those referred to in the first subparagraph in any one of the following situations:

(a) where the Member State in which it is established has decided not to establish a national accreditation body and has not had recourse to the national accreditation body of another Member State in accordance with Article 4(2);

(b) where the national accreditation bodies referred to in the first subparagraph do not perform accreditation in respect of the conformity assessment activities for which accreditation is sought;

(c) where the national accreditation bodies referred to in the first subparagraph have not successfully undergone peer evaluation under Article 10 in respect of the conformity assessment activities for which accreditation is sought.

2. Where a national accreditation body receives a request pursuant to paragraph 1(b) or (c), it shall inform the national accreditation body of the Member State in which the requesting conformity assessment body is established. In such cases, the national accreditation body of the Member State in which the requesting conformity assessment body is established may participate as an observer.

3. A national accreditation body may request another national accreditation body to carry out part of the assessment activity. In such a case, the accreditation certificate shall be issued by the requesting body.

Article 8

Requirements for national accreditation bodies

A national accreditation body shall fulfil the following requirements:

1. it shall be organised in such a manner as to make it independent of the conformity assessment bodies it assesses and of commercial pressures, and to ensure that no conflicts of interest with conformity assessment bodies occur;

2. it shall be organised and operated so as to safeguard the objectivity and impartiality of its activities;

3. it shall ensure that each decision relating to the attestation of competence is taken by competent persons different from those who carried out the assessment;

4. it shall have adequate arrangements to safeguard the confidentiality of the information obtained;

5. it shall identify the conformity assessment activities for which it is competent to perform accreditation, referring, where appropriate, to relevant Community or national legislation and standards;

6. it shall set up the procedures necessary to ensure efficient management and appropriate internal controls;

7. it shall have a number of competent personnel at its disposal sufficient for the proper performance of its tasks;

8. it shall document the duties, responsibilities and authorities of personnel who could affect the quality of the assessment and of the attestation of competence;

9. it shall establish, implement and maintain procedures for monitoring the performance and competence of the personnel involved;

10. it shall verify that conformity assessments are carried out in an appropriate manner, meaning that unnecessary burdens are not imposed on undertakings and that due account is taken of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process;

11. it shall publish audited annual accounts prepared in accordance with generally accepted accounting principles.

Article 9

Compliance with requirements

1. Where a national accreditation body does not meet the requirements of this Regulation or fails to fulfil its obligations hereunder, the Member State concerned shall take appropriate corrective action or shall ensure that such corrective action is taken, and shall inform the Commission thereof.

2. Member States shall monitor their national accreditation bodies at regular intervals in order to ensure that they fulfil the requirements laid down in Article 8 on a continuing basis.

3. Member States shall take the utmost account of the results of peer evaluation under Article 10 when carrying out the monitoring referred to in paragraph 2 of this Article.

4. National accreditation bodies shall have in place the necessary procedures to deal with complaints against the conformity assessment bodies they have accredited.

Article 10

Peer evaluation

1. National accreditation bodies shall subject themselves to peer evaluation organised by the body recognised under Article 14.

2. Stakeholders shall have the right to participate in the system set up for the supervision of peer evaluation activities, but not in individual peer evaluation procedures.

3. Member States shall ensure that their national accreditation bodies regularly undergo peer evaluation as required by paragraph 1.

4. Peer evaluation shall be operated on the basis of sound and transparent evaluation criteria and procedures, in particular concerning structural, human resource and process requirements, confidentiality and complaints. Appropriate appeal procedures against decisions taken as a result of such evaluation shall be provided for.

5. Peer evaluation shall ascertain whether the national accreditation bodies meet the requirements laid down in Article 8, taking into account the relevant harmonised standards referred to in Article 11.

6. The outcome of peer evaluation shall be published and communicated by the body recognised under Article 14 to all Member States and the Commission.

7. The Commission shall, in cooperation with the Member States, oversee the rules and the proper functioning of the peer evaluation system.

Article 11

Presumption of conformity for national accreditation bodies

1. National accreditation bodies that demonstrate conformity with the criteria laid down in the relevant harmonised standard, the reference of which has been published in the *Official Journal of the European Union*, by having successfully undergone peer evaluation under Article 10 shall be presumed to fulfil the requirements laid down in Article 8.

2. National authorities shall recognise the equivalence of the services delivered by those accreditation bodies which have successfully undergone peer evaluation under Article 10, and thereby accept, on the basis of the presumption referred to in paragraph 1 of this Article, the accreditation certificates of those bodies and the attestations issued by the conformity assessment bodies accredited by them.

Article 12

Information obligation

1. Each national accreditation body shall inform the other national accreditation bodies of the conformity assessment activities in respect of which it operates accreditation and of any changes thereto.

2. Each Member State shall inform the Commission and the body recognised under Article 14 of the identity of its national accreditation body and of all conformity assessment activities in respect of which that body operates accreditation in support of Community harmonisation legislation, and of any changes thereto.

3. Each national accreditation body shall regularly make publicly available information concerning the results of its peer evaluation, the conformity assessment activities in respect of which it operates accreditation and any changes thereto.

Article 13

Requests to the body recognised under Article 14

1. The Commission may, after consulting the Committee set up by Article 5 of Directive 98/34/EC, request the body recognised under Article 14 to contribute to the development, maintenance and implementation of accreditation in the Community.

2. The Commission may also, following the procedure laid down in paragraph 1:

(a) request the body recognised under Article 14 to lay down evaluation criteria and procedures for peer evaluation and to develop sectoral accreditation schemes;

(b) accept any existing scheme that already lays down evaluation criteria and procedures for peer evaluation.

3. The Commission shall ensure that sectoral schemes identify the technical specifications necessary to meet the level of competence required by Community harmonisation legislation in fields with specific requirements relating to technology, health and safety or environment related requirements or any other aspect of public interest protection.

Article 14

European accreditation infrastructure

1. The Commission shall, after consulting the Member States, recognise a body which satisfies the requirements set out in Annex I to this Regulation.

2. A body which is to be recognised pursuant to paragraph 1 shall conclude an agreement with the Commission. That agreement shall specify, *inter alia*, the detailed tasks of the body, funding provisions and provisions for its supervision. Both the Commission and the body shall be able to terminate the agreement without cause at the expiry of a reasonable period of notice to be defined therein.

3. The Commission and the body shall make the agreement public.

4. The Commission shall communicate the recognition of a body pursuant to paragraph 1 to the Member States and to national accreditation bodies.

5. The Commission may not recognise more than one body at a time.

6. The first body recognised under this Regulation shall be the European cooperation for accreditation, provided that it has concluded an agreement as specified in paragraph 2.

CHAPTER III

COMMUNITY MARKET SURVEILLANCE FRAMEWORK AND CONTROLS OF PRODUCTS ENTERING THE COMMUNITY MARKET

SECTION 1

General provisions

Article 15

Scope

1. Articles 16 to 26 shall apply to products covered by Community harmonisation legislation.

2. Each of the provisions of Articles 16 to 26 shall apply in so far as there are no specific provisions with the same objective in Community harmonisation legislation.

3. The application of this Regulation shall not prevent market surveillance authorities from taking more specific measures as provided for in Directive 2001/95/EC.

4. For the purposes of Articles 16 to 26, a 'product' shall mean a substance, preparation or good produced through a manufacturing process other than food, feed, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction.

5. Articles 27, 28 and 29 shall apply to all products covered by Community legislation in so far as other Community legislation does not contain specific provisions relating to the organisation of border controls.

Article 16

General requirements

1. Member States shall organise and carry out market surveillance as provided for in this Chapter.

2. Market surveillance shall ensure that products covered by Community harmonisation legislation which, when used in accordance with their intended purpose or under conditions which can be reasonably foreseen and when properly installed and maintained, are liable to compromise the health or safety of users, or which otherwise do not conform to applicable requirements set out in Community harmonisation legislation are withdrawn or their being made available on the market is prohibited or restricted and that the public, the Commission and the other Member States are informed accordingly.

3. National market surveillance infrastructures and programmes shall ensure that effective measures can be taken in relation to any product category subject to Community harmonisation legislation.

4. Market surveillance shall cover products assembled or manufactured for the manufacturer's own use where Community harmonisation legislation provides that its provisions shall apply to such products.

SECTION 2

Community market surveillance framework

Article 17

Information obligations

1. Member States shall inform the Commission of their market surveillance authorities and their areas of competence. The Commission shall transmit that information to the other Member States.

2. Member States shall ensure that the public is aware of the existence, responsibilities and identity of national market surveillance authorities, and of how those authorities may be contacted.

Article 18

Obligations of the Member States as regards organisation

1. Member States shall establish appropriate communication and coordination mechanisms between their market surveillance authorities.

2. Member States shall establish adequate procedures in order to:

(a) follow up complaints or reports on issues relating to risks arising in connection with products subject to Community harmonisation legislation;

(b) monitor accidents and harm to health which are suspected to have been caused by those products;

(c) verify that corrective action has been taken; and

(d) follow up scientific and technical knowledge concerning safety issues.

3. Member States shall entrust market surveillance authorities with the powers, resources and knowledge necessary for the proper performance of their tasks.

4. Member States shall ensure that market surveillance authorities exercise their powers in accordance with the principle of proportionality.

5. Member States shall establish, implement and periodically update their market surveillance programmes. Member States shall draw up either a general market surveillance programme or sector specific programmes, covering the sectors in which they conduct market surveillance, communicate those programmes to the other Member States and the Commission and make them

available to the public, by way of electronic communication and, where appropriate, by other means. The first such communication shall be effected by 1 January 2010. Subsequent updates of the programmes shall be made public in the same manner. Member States may cooperate with all relevant stakeholders to those ends.

6. Member States shall periodically review and assess the functioning of their surveillance activities. Such reviews and assessments shall be carried out at least every fourth year and the results thereof shall be communicated to the other Member States and the Commission and be made available to the public, by way of electronic communication and, where appropriate, by other means.

Article 19

Market surveillance measures

1. Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks on the basis of adequate samples. When doing so they shall take account of established principles of risk assessment, complaints and other information.

Market surveillance authorities may require economic operators to make such documentation and information available as appear to them to be necessary for the purpose of carrying out their activities, and, where it is necessary and justified, enter the premises of economic operators and take the necessary samples of products. They may destroy or otherwise render inoperable products presenting a serious risk where they deem it necessary.

Where economic operators present test reports or certificates attesting conformity issued by an accredited conformity assessment body, market surveillance authorities shall take due account of such reports or certificates.

2. Market surveillance authorities shall take appropriate measures to alert users within their territories within an adequate timeframe of hazards they have identified relating to any product so as to reduce the risk of injury or other damage.

They shall cooperate with economic operators regarding actions which could prevent or reduce risks caused by products made available by those operators.

3. Where the market surveillance authorities of one Member State decide to withdraw a product manufactured in another Member State, they shall inform the economic operator concerned at the address indicated on the product in question or in the documentation accompanying that product.

4. Market surveillance authorities shall carry out their duties independently, impartially and without bias.

5. Market surveillance authorities shall observe confidentiality where necessary in order to protect commercial secrets or to preserve personal data pursuant to national legislation, subject to the requirement that information be made public under this Regulation to the fullest extent necessary in order to protect the interests of users in the Community.

Article 20

Products presenting a serious risk

1. Member States shall ensure that products which present a serious risk requiring rapid intervention, including a serious risk the effects of which are not immediate, are recalled, withdrawn or that their being made available on their market is prohibited, and that the Commission is informed without delay thereof, in accordance with Article 22.

2. The decision whether or not a product represents a serious risk shall be based on an appropriate risk assessment which takes account of the nature of the hazard and the likelihood of its occurrence. The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering that a product presents a serious risk.

Article 21

Restrictive measures

1. Member States shall ensure that any measure taken, pursuant to the relevant Community harmonisation legislation, to prohibit or restrict the product's being made available on the market, to withdraw it from the market or to recall it, is proportionate and states the exact grounds on which it is based.

2. Such measures shall be communicated without delay to the relevant economic operator, which shall at the same time be informed of the remedies available under the law of the Member State concerned and of the time limits to which such remedies are subject.

3. Prior to the adoption of a measure referred to in paragraph 1, the economic operator concerned shall be given the opportunity to be heard within an appropriate period of not less than 10 days, unless such consultation is not possible because of the urgency of the measure to be taken, as justified by health or safety requirements or other grounds relating to the public interests covered by the relevant Community harmonisation legislation. If action has been taken without the operator's being heard, the operator shall be given the opportunity to be heard as soon as possible and the action taken shall be reviewed promptly thereafter.

4. Any measure referred to in paragraph 1 shall be promptly withdrawn or amended upon the economic operator's demonstrating that he has taken effective action.

Article 22

Exchange of information — Community Rapid Information System

1. Where a Member State takes or intends to take a measure in accordance with Article 20 and considers that the reasons which prompted the measure or the effects of the measure go beyond its territory, it shall immediately notify the Commission of that measure, in accordance with paragraph 4 of this Article. It shall also inform the Commission without delay of the modification or withdrawal of any such measure.

2. If a product presenting a serious risk has been made available on the market, Member States shall notify the Commission of any voluntary measures taken and communicated by an economic operator.

3. The information provided in accordance with paragraphs 1 and 2 shall include all available details, in particular the data necessary for the identification of the product, the origin and the supply chain of the product, the related risk, the nature and the duration of the national measure taken and any voluntary measures taken by economic operators.

4. For the purposes of paragraphs 1, 2 and 3, the market surveillance and information exchange system provided for in Article 12 of Directive 2001/95/EC shall be used. Paragraphs 2, 3 and 4 of Article 12 of that Directive shall apply *mutatis mutandis*.

Article 23

General information support system

1. The Commission shall develop and maintain a general archiving and exchange of information system, using electronic means, on issues relating to market surveillance activities, programmes and related information on non-compliance with Community harmonisation legislation. The system shall appropriately reflect notifications and information provided under Article 22.

2. For the purposes of paragraph 1, Member States shall provide the Commission with information at their disposal and not already provided under Article 22 on products presenting a risk regarding, in particular, identification of risks, results of testing carried out, provisional restrictive measures taken, contacts with the economic operators concerned and justification for action or inaction.

3. Without prejudice to Article 19(5) or to national legislation in the area of confidentiality, the safeguarding of confidentiality with regard to the information content shall be ensured. The protection of confidentiality shall not prevent the dissemination to market surveillance authorities of information relevant to ensuring the effectiveness of market surveillance activities.

Article 24

Principles of cooperation between the Member States and the Commission

1. Member States shall ensure efficient cooperation and exchange of information between their market surveillance authorities and those of the other Member States and between their own authorities and the Commission and the relevant Community agencies regarding their market surveillance programmes and all issues relating to products presenting risks.

2. For the purposes of paragraph 1, the market surveillance authorities of one Member State shall give the market surveillance authorities of other Member States assistance on an adequate scale by supplying information or documentation, by carrying out appropriate investigations or any other appropriate measure and by participating in investigations initiated in other Member States.

3. The Commission shall collect and organise such data on national market surveillance measures as will enable it to fulfil its obligations.

4. Any information provided by an economic operator under Article 21(3) or otherwise shall be included when the reporting Member State notifies other Member States and the Commission of its findings and actions. Any subsequent information shall be clearly identified as relating to the information already provided.

Article 25

Sharing of resources

1. Market surveillance initiatives designed to share resources and expertise between the competent authorities of the Member States may be set up by the Commission or the Member States concerned. Such initiatives shall be coordinated by the Commission.

2. For the purposes of paragraph 1, the Commission shall, in cooperation with the Member States:

(a) develop and organise training programmes and exchanges of national officials;

(b) develop, organise and set up programmes for the exchange of experience, information and best practice, programmes and actions for common projects, information campaigns, joint visit programmes and the consequent sharing of resources.

3. Member States shall ensure that their competent authorities participate fully in the activities referred to in paragraph 2, where appropriate.

Article 26

Cooperation with the competent authorities of third countries

1. Market surveillance authorities may cooperate with the competent authorities of third countries with a view to exchanging information and technical support, promoting and facilitating access to European systems and promoting activities relating to conformity assessment, market surveillance and accreditation.

The Commission shall, in cooperation with Member States, develop appropriate programmes for that purpose.

2. Cooperation with the competent authorities of third countries shall take the form of, *inter alia*, the activities referred to in Article 25(2). Member States shall ensure that their competent authorities participate fully in those activities.

SECTION 3

Controls of products entering the Community market

Article 27

Controls of products entering the Community market

1. The authorities of the Member States in charge of the control of products entering the Community market shall have the powers and resources necessary for the proper performance of their tasks. They shall carry out appropriate checks on the characteristics of products on an adequate scale, in accordance with the principles set out in Article 19(1), before those products are released for free circulation.

2. Where in a Member State more than one authority is responsible for market surveillance or external border controls, those authorities shall cooperate with each other, by sharing information relevant to their functions and otherwise as appropriate.

3. The authorities in charge of external border controls shall suspend release of a product for free circulation on the Community market when any of the following findings are made in the course of the checks referred to in paragraph 1:

(a) the product displays characteristics which give cause to believe that the product, when properly installed, maintained and used, presents a serious risk to health, safety, the environment or any other public interest referred to in Article 1;

(b) the product is not accompanied by the written or electronic documentation required by the relevant Community harmonisation legislation or is not marked in accordance with that legislation;

(c) the CE marking has been affixed to the product in a false or misleading manner.

The authorities in charge of external border controls shall immediately notify the market surveillance authorities of any such suspension.

4. In the case of perishable products, the authorities in charge of external border controls shall, as far as possible, seek to ensure that any requirements they may impose with regard to the storage of products or the parking of vehicles used for transport are not incompatible with the preservation of those products.

5. For the purposes of this Section, Article 24 shall apply in respect of authorities in charge of external border controls, without prejudice to the application of Community law providing for more specific systems of cooperation between those authorities.

Article 28

Release of products

1. A product the release of which has been suspended by the authorities in charge of external border controls pursuant to Article 27 shall be released if, within three working days of the suspension of release, those authorities have not been notified of any action taken by the market surveillance authorities, and provided that all the other requirements and formalities pertaining to such release have been fulfilled.

2. Where the market surveillance authorities find that the product in question does not present a serious risk to health and safety or cannot be regarded as being in breach of Community harmonisation legislation, that product shall be released, provided that all the other requirements and formalities pertaining to such release have been fulfilled.

Article 29

National measures

1. Where the market surveillance authorities find that a product presents a serious risk, they shall take measures to prohibit that product from being placed on the market and shall require the authorities in charge of external border controls to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document or, where data processing is carried out electronically, in the data-processing system itself:

'Dangerous product — release for free circulation not authorised — Regulation (EC) No 765/2008'.

2. Where the market surveillance authorities find that a product does not comply with Community harmonisation legislation, they shall take appropriate action, which may, if necessary, include prohibiting the product's being placed on the market.

Where placing on the market is prohibited pursuant to the first subparagraph, the market surveillance authorities shall require the authorities in charge of external border controls not to release the product for free circulation and to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document or, where data processing is carried out electronically, in the data-processing system itself:

'Product not in conformity — release for free circulation not authorised — Regulation (EC) No 765/2008'.

3. Where that product is subsequently declared for a customs procedure other than release for free circulation and provided that the market surveillance authorities do not object, the endorsements set out in paragraphs 1 and 2 shall also be included, under the same conditions, on the documents used in connection with that procedure.

4. Member States' authorities may destroy or otherwise render inoperable products presenting a serious risk where they deem it necessary and proportionate.

5. Market surveillance authorities shall provide authorities in charge of external border controls with information on product categories in which a serious risk or non-compliance within the meaning of paragraphs 1 and 2 has been identified.

CHAPTER IV

CE MARKING

Article 30

General principles of the CE marking

1. The CE marking shall be affixed only by the manufacturer or his authorised representative.

2. The CE marking as presented in Annex II shall be affixed only to products to which its affixing is provided for by specific Community harmonisation legislation, and shall not be affixed to any other product.

3. By affixing or having affixed the CE marking, the manufacturer indicates that he takes responsibility for the conformity of the product with all applicable requirements set out in the relevant Community harmonisation legislation providing for its affixing.

4. The CE marking shall be the only marking which attests the conformity of the product with the applicable requirements of the relevant Community harmonisation legislation providing for its affixing.

5. The affixing to a product of markings, signs or inscriptions which are likely to mislead third parties regarding the meaning or form of the CE marking shall be prohibited. Any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.

6. Without prejudice to Article 41, Member States shall ensure the correct implementation of the regime governing the CE marking and take appropriate action in the event of improper use of the marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.

CHAPTER V

COMMUNITY FINANCING

Article 31

Body pursuing an aim of general European interest

The body recognised under Article 14 shall be considered a body pursuing an aim of general European interest within the meaning of Article 162 of Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Regulation (EC, Euratom) No 1605/2002 ([1]).

Article 32

Activities eligible for Community financing

1. The Community may finance the following activities in connection with the application of this Regulation:

(a) the production and revision of sectoral accreditation schemes referred to in Article 13(3);

(b) the activities of the secretariat of the body recognised under Article 14, such as the coordination of accreditation activities, the processing of technical work linked to the operation of the peer evaluation system, the provision of interested parties with information and the participation of the body in the activities of international organisations in the field of accreditation;

(c) the drawing up and updating of contributions to guidelines in the fields of accreditation, notification to the Commission of conformity assessment bodies, conformity assessment and market surveillance;

(d) inter-comparison activities linked to the operation of safeguard clauses;

(e) the making available to the Commission of technical expertise for the purpose of assisting the Commission in its implementation of market surveillance administrative cooperation, including the financing of administrative cooperation groups, market surveillance decisions and safeguard clause cases;

(f) the performance of preliminary or ancillary work in connection with the implementation of the conformity assessment, metrology, accreditation and market surveillance activities linked to the implementation of Community legislation, such as studies, programmes, evaluations, guidelines, comparative analyses, mutual joint visits, research work, the development and maintenance of databases, training activities, laboratory work, proficiency testing, inter-laboratory tests and conformity assessment work, as well as European market surveillance campaigns and similar activities;

([1]) OJ L 357, 31.12.2002, p. 1. Regulation as last amended by Regulation (EC, Euratom) No 478/2007 (OJ L 111, 28.4.2007, p. 13).

(g) activities carried out under programmes of technical assistance, cooperation with third countries and the promotion and enhancement of European conformity assessment, market surveillance and accreditation policies and systems among interested parties in the Community and at international level.

2. The activities referred to in paragraph 1(a) shall be eligible for Community financing only if the Committee set up by Article 5 of Directive 98/34/EC has been consulted on the requests to be submitted to the body recognised under Article 14 of this Regulation.

Article 33

Bodies eligible for Community financing

Community financing may be granted to the body recognised under Article 14 for the implementation of the activities set out in Article 32.

However, Community financing may also be granted to other bodies for the carrying out of the activities set out in Article 32, except those set out in paragraph 1(a) and (b) of that Article.

Article 34

Financing

The appropriations allocated to the activities referred to in this Regulation shall be determined each year by the budgetary authority within the limits of the financial framework in force.

Article 35

Financing arrangements

1. Community financing shall be provided:

(a) without a call for proposals, to the body recognised under Article 14 to carry out those activities referred to in Article 32(1)(a) to (g) for which grants can be awarded in accordance with the Financial Regulation;

(b) in the form of grants after a call for proposals, or by public procurement procedures, to other bodies to carry out the activities referred to in Article 32(1)(c) to (g).

2. The activities of the secretariat of the body recognised under Article 14 referred to in Article 32(1)(b) may be financed on the basis of operating grants. In the event of renewal, the operating grants shall not be decreased automatically.

3. Grant agreements may authorise flat-rate cover of the beneficiary's overheads up to a maximum of 10 % of total eligible direct costs for actions, except where the beneficiary's indirect costs are covered through an operating grant financed from the Community budget.

4. The common cooperation objectives and the administrative and financial conditions relating to the grants awarded to the body recognised under Article 14 may be defined in a framework partnership agreement signed by the Commission and that body, in accordance with the Financial Regulation and Regulation (EC, Euratom) No 2342/2002. The European Parliament and the Council shall be informed of the conclusion of any such agreement.

Article 36

Management and monitoring

1. The appropriations determined by the budgetary authority for the financing of conformity assessment, accreditation and market surveillance activities may also cover administrative expenses relating to preparation, monitoring, inspection, auditing and evaluation which are directly necessary for the achievement of the objectives of this Regulation, and in particular studies, meetings, information and publication activities, expenses relating to informatics networks for the exchange of information and any other expenditure on administrative and technical assistance which the Commission may use for conformity assessment and accreditation activities.

2. The Commission shall evaluate the relevance of the conformity assessment, accreditation and market surveillance activities that receive Community financing in the light of the requirements of Community policies and legislation, and inform the European Parliament and the Council of the outcome of that evaluation by 1 January 2013 and every five years thereafter.

Article 37

Protection of the Community's financial interests

1. The Commission shall ensure that, when the activities financed under this Regulation are implemented, the Community's financial interests are protected by the application of preventive measures against fraud, corruption and other illegal activities, by effective checks and by the recovery of amounts unduly paid and, if irregularities are detected, by effective, proportionate and dissuasive penalties, in accordance with Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests ([1]), Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities ([2]) and Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF) ([3]).

2. For the purposes of the Community activities financed under this Regulation, the notion of irregularity referred to in

([1]) OJ L 312, 23.12.1995, p. 1.
([2]) OJ L 292, 15.11.1996, p. 2.
([3]) OJ L 136, 31.5.1999, p. 1.

Article 1(2) of Regulation (EC, Euratom) No 2988/95 shall mean any infringement of a provision of Community law or any breach of a contractual obligation resulting from an act or omission by an economic operator which has, or would have, the effect of prejudicing the general budget of the European Union or budgets managed by it by an unjustified item of expenditure.

3. Any agreements and contracts resulting from this Regulation shall provide for monitoring and financial control by the Commission or any representative which it authorises and for audits by the Court of Auditors, which may be conducted on the spot if necessary.

CHAPTER VI

FINAL PROVISIONS

Article 38

Technical guidelines

In order to facilitate the implementation of this Regulation, the Commission shall draw up non-binding guidelines in consultation with stakeholders.

Article 39

Transitional provision

Accreditation certificates issued before 1 January 2010 may remain valid until the date of their expiry, but no later than 31 December 2014. This Regulation shall, however, apply in the case of their extension or renewal.

Article 40

Review and reporting

By 2 September 2013, the Commission shall submit to the European Parliament and to the Council a report on the application of this Regulation, of Directive 2001/95/EC and of any other relevant Community instrument addressing market surveillance. That report shall, in particular, analyse the consistency of Community rules in the field of market surveillance. If appropriate, it shall be accompanied by proposals to amend and/or consolidate the instruments concerned, in the interests of better regulation and simplification. It shall include an evaluation of the extension of the scope of Chapter III of this Regulation to all products.

By 1 January 2013, and every five years thereafter, the Commission, in cooperation with the Member States, shall produce and submit to the European Parliament and to the Council a report on the implementation of this Regulation.

Article 41

Penalties

The Member States shall lay down rules on penalties for economic operators, which may include criminal sanctions for serious infringements, applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive and may be increased if the relevant economic operator has previously committed a similar infringement of the provisions of this Regulation. The Member States shall notify the Commission of those provisions by 1 January 2010 and shall notify it without delay of any subsequent amendment affecting them.

Article 42

Amendment to Directive 2001/95/EC

Article 8(3) of Directive 2001/95/EC shall be replaced by the following:

'3. In the case of products posing a serious risk, the competent authorities shall with due dispatch take the appropriate measures referred to in paragraph 1(b) to (f). The existence of a serious risk shall be determined by the Member States, assessing each individual case on its merits and taking into account the guidelines referred to in point 8 of Annex II.'.

Article 43

Repeal

Regulation (EEC) No 339/93 is hereby repealed with effect from 1 January 2010.

References to the repealed Regulation shall be construed as references to this Regulation.

Article 44

Entry into force

This Regulation shall enter into force on the 20th day after its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 9 July 2008.

For the European Parliament	*For the Council*
The President	*The President*
H.-G. PÖTTERING	J.-P. JOUYET

ANNEX I

Requirements applicable to the body to be recognised under Article 14

1. The body recognised under Article 14 of the Regulation (the body), shall be established within the Community.

2. Under the body's constitution, national accreditation bodies from within the Community shall be entitled to be members of it, provided that they comply with the rules and objectives of the body and with the other conditions set out herein and as agreed with the Commission in the framework agreement.

3. The body shall consult all relevant stakeholders.

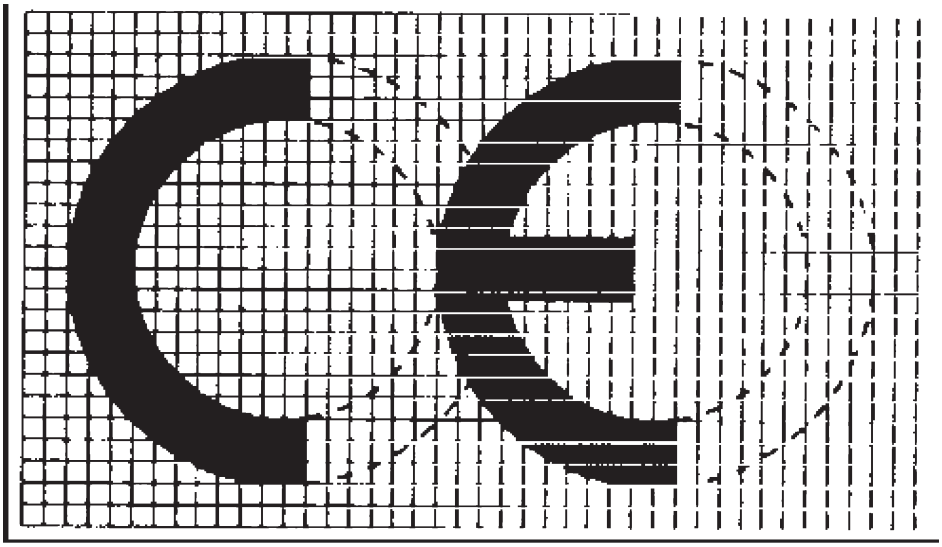
4. The body shall provide its members with peer evaluation services satisfying the requirements of Articles 10 and 11.

5. The body shall cooperate with the Commission in accordance with this Regulation.

ANNEX II

CE marking

1. The CE marking shall consist of the initials 'CE' taking the following form:



2. If the CE marking is reduced or enlarged, the proportions given in the graduated drawing in paragraph 1 shall be respected.

3. Where specific legislation does not impose specific dimensions, the CE marking shall be at least 5 mm high.

REGULATION (EC) No 766/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 July 2008

amending Council Regulation (EC) No 515/97 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 135 and 280 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Court of Auditors [1],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [2],

Whereas:

(1) Council Regulation (EC) No 515/97 [3] improved the earlier legal mechanism, in particular by allowing information to be stored in the Community database Customs Information System (CIS).

(2) However, experience gained since Regulation (EC) No 515/97 entered into force has shown that the use of the CIS for the sole purposes of sighting and reporting, discreet surveillance or specific checks does not make it possible to achieve fully the system's objective, which is to assist in preventing, investigating and prosecuting operations that are in breach of customs or agricultural legislation.

(3) The changes introduced when the European Union was enlarged to include 27 Member States require a reconsideration of Community customs cooperation in a broader framework and with modernised mechanisms.

(4) Commission Decision 1999/352/EC, ECSC, Euratom of 28 April 1999 establishing the European Anti-Fraud Office (OLAF) [4] and the Convention on the use of information technology for customs purposes [5], drawn up by Council Act of 26 July 1995 [6], modified the general framework for cooperation between the Member States and the Commission as regards preventing, investigating and prosecuting offences under Community legislation.

(5) The results of strategic analysis should help those responsible at the highest level to determine projects, objectives and policies for combating fraud, to plan activities and to deploy the resources needed to achieve the operational objectives laid down.

(6) The result of an operational analysis concerning the activities, resources and intentions of certain persons or businesses that do not comply or appear not to comply with customs or agricultural legislation should help the customs authorities and the Commission take the appropriate measures in specific cases to achieve the objectives laid down as regards the fight against fraud.

(7) Under the current mechanism set out in Regulation (EC) No 515/97, personal data entered by a Member State can be copied from CIS into other data-processing systems only with the prior authorisation of the CIS partner which entered them and subject to the conditions imposed by it in accordance with Article 30(1). The amendment of the Regulation is designed to derogate from that principle of prior authorisation only where the data are to be processed by the national authorities and the Commission services responsible for risk management with a view to targeting controls on movements of goods.

(8) The current mechanism needs to be supplemented by a legal framework establishing a customs files identification database covering past and current files. The creation of such a database follows up the intergovernmental customs cooperation initiative which led to the adoption of the Council Act of 8 May 2003 drawing up the Protocol amending, as regards the creation of a customs files identification database, the Convention on the use of information technology for customs purposes [7].

[1] OJ C 101, 4.5.2007, p. 4.

[2] Opinion of the European Parliament of 19 February 2008 (not yet published in the Official Journal) and Council Decision of 23 June 2008.

[3] OJ L 82, 22.3.1997, p. 1. Regulation amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

[4] OJ L 136, 31.5.1999, p. 20.

[5] OJ C 316, 27.11.1995, p. 34.

[6] OJ C 316, 27.11.1995, p. 33.

[7] OJ C 139, 13.6.2003, p. 1.

(9) It is necessary to ensure that, in order to strengthen customs cooperation between Member States and between Member States and the Commission, and without prejudice to other provisions of Regulation (EC) No 515/97, certain data may be exchanged in pursuit of the objectives of that Regulation.

(10) In addition, it is necessary to ensure greater complementarity with action in the context of intergovernmental customs cooperation and of cooperation with the other bodies and agencies of the European Union and other international and regional organisations. Such action follows on from the Council Resolution of 2 October 2003 concerning a strategy for customs cooperation ([1]) and the Council Decision of 6 December 2001 extending the mandate of Europol to the fight against the serious forms of international crime listed in the Annex to the Europol Convention ([2]).

(11) In order to promote coherence between the action taken by the Commission, the other bodies and agencies of the European Union and other international and regional organisations, the Commission should be authorised to provide training and all forms of assistance other than financial assistance for the liaison officers of third countries and of European and international organisations and agencies, including the exchange of best practice with those bodies, and, for example, with Europol and the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union (Frontex).

(12) The conditions should be created under Regulation (EC) No 515/97 for the implementation of joint customs operations in the Community context. The Committee provided for by Article 43 of Regulation (EC) No 515/97 should be empowered to determine the mandate for Community joint customs operations.

(13) A permanent infrastructure must be created within the Commission so that joint customs operations can be coordinated throughout the calendar year and representatives of the Member States and, if necessary, liaison officers from third countries or European or international organisations and agencies, in particular Europol and the World Customs Organisation (WCO) and Interpol, can be hosted for the time needed to carry out one or more individual operations.

(14) In order to address CIS-related supervision issues, the European Data Protection Supervisor should convene a meeting with national data protection supervisory authorities at least once a year.

(15) The Member States must have the possibility of reusing that infrastructure for joint customs operations organised by way of customs cooperation as provided for in Articles 29 and 30 of the Treaty on European Union, without prejudice to the role of Europol. In that event, joint customs operations should be conducted under the mandate determined by the relevant Council working party as regards customs cooperation under Title VI of the Treaty on European Union.

(16) In addition, the development of new markets, the increasing internationalisation of trade and the rapid expansion thereof, combined with the increase in the speed of the carriage of goods, require customs administrations to keep up with movement so as not to harm the development of Europe's economy.

(17) The ultimate objectives are that all operators should be able to provide all necessary documentation in advance and fully computerise their connections with the customs authorities. Meanwhile, the current situation will continue to exist, with various levels of development of national computer systems, and anti-fraud mechanisms must be improved since deflections of trade can still occur.

(18) For the purpose of the fight against fraud, it is therefore necessary, together with the reform and modernisation of customs systems, to seek information at the furthest possible point upstream. In addition, in order to help the competent authorities of the Member States to detect movements of goods that are the object of operations in potential breach of customs or agricultural legislation and means of transport, including containers, used for that purpose, data from the principal service suppliers worldwide, public or private, that are active in the international supply chain should be pooled in a European central data directory.

(19) The protection of natural persons in the processing of personal data is governed by Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ([3]) and by Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) ([4]), which are fully applicable to information society services. Those Directives already establish a Community legal framework in the field of personal data and therefore it is not necessary

([1]) OJ C 247, 15.10.2003, p. 1.
([2]) OJ C 362, 18.12.2001, p. 1.
([3]) OJ L 281, 28.11.1995, p. 31. Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).
([4]) OJ L 201, 31.7.2002, p. 37. Directive as amended by Directive 2006/24/EC (OJ L 105, 13.4.2006, p. 54).

to cover the issue in this Regulation in order to ensure the smooth functioning of the internal market, in particular the free movement of personal data between Member States. This Regulation must be implemented and applied in accordance with the rules on the protection of personal data, in particular as regards the exchange and storage of information in support of action to prevent and detect fraud.

(20) The exchange of personal data with third countries should be subject to prior verification that data protection rules in the receiving country offer a degree of protection equivalent to that provided by Community law.

(21) As Directive 95/46/EC has been transposed by the Member States since the adoption of Regulation (EC) No 515/97, and the Commission has established an independent authority to ensure that freedoms and fundamental rights of persons are respected by Community institutions and bodies in the processing of personal data in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data [1], the personal data protection control measures should be aligned and the reference to the European Ombudsman should be replaced by a reference to the European Data Protection Supervisor, without prejudice to the powers of the Ombudsman.

(22) The measures necessary for the implementation of Regulation (EC) No 515/97 should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [2].

(23) In particular, the Commission should be empowered to decide on items to be included in the CIS and to determine operations concerning the application of agricultural legislation in respect of which information is to be entered therein. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 515/97, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(24) The report on the implementation of Regulation (EC) No 515/97 should be integrated in the report submitted each year to the European Parliament and to the Council on the measures taken in implementation of Article 280 of the Treaty.

(25) Regulation (EC) No 515/97 should be amended accordingly.

(26) Since the objective of this Regulation, namely the coordination of the fight against fraud and any other illegal activity to the detriment of the Community's financial interests, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Community level, the Community may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(27) This Regulation respects fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union [3]. In particular, this Regulation aims to ensure full respect for the right to the protection of personal data (Article 8 of the Charter of Fundamental Rights of the European Union).

(28) The European Data Protection Supervisor has been consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 and delivered an opinion on 22 February 2007 [4],

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 515/97 is hereby amended as follows:

1. in Article 2(1), the following indents shall be added:

'— "operational analysis" means analysis of operations which constitute, or appear to constitute, breaches of customs or agricultural legislation, involving the following stages in turn:

(a) the collection of information, including personal data;

(b) evaluation of the reliability of the information source and the information itself;

(c) research, methodical presentation and interpretation of links between these items of information or between them and other significant data;

[1] OJ L 8, 12.1.2001, p. 1.
[2] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).
[3] OJ C 364, 18.12.2000, p. 1.
[4] OJ C 94, 28.4.2007, p. 3.

(d) the formulation of observations, hypotheses or recommendations directly usable as risk information by the competent authorities and by the Commission to prevent and detect other operations in breach of customs and agricultural legislation and/or to identify with precision the person or businesses implicated in such operations,

— "strategic analysis" means research and presentation of the general trends in breaches of customs and agricultural legislation through an evaluation of the threat, scale and impact of certain types of operation in breach of customs and agricultural legislation, with a view to subsequently setting priorities, gaining a better picture of the phenomenon or threat, reorienting action to prevent and detect fraud and reviewing departmental organisation. Only data from which identifying factors have been removed may be used for strategic analysis,

— "regular automatic exchange" means the systematic communication of predefined information, without prior request, at pre-established regular intervals,

— "occasional automatic exchange" means the systematic communication of predefined information, without prior request, as and when that information becomes available.';

2. the following Article shall be inserted:

'Article 2a

Without prejudice to other provisions of this Regulation, and in pursuit of the objectives thereof, in particular where no customs declaration or simplified declaration is presented or where it is incomplete or where there is a reason to believe that the data contained therein are false, the Commission or the competent authorities of each Member State may exchange with the competent authority of any other Member State or the Commission the following data:

(a) business name;

(b) trading name;

(c) address of the business;

(d) VAT identification number of the business;

(e) excise duties identification number (*);

(f) information as to whether the VAT identification number and/or the excise duties identification number is in use;

(g) names of the managers, directors and, if available, principal shareholders of the business;

(h) number and date of issue of the invoice; and

(i) amount invoiced.

This Article shall apply only to movements of goods as described in the first indent of Article 2(1).

(*) As provided for in Article 22(2)(a) of Council Regulation (EC) No 2073/2004 of 16 November 2004 on administrative cooperation in the field of excise duties (OJ L 359, 4.12.2004, p. 1.).';

3. Article 15 shall be amended as follows:

(a) the existing paragraph shall be numbered as paragraph 1;

(b) the following paragraph shall be added:

'2. The competent authorities of each Member State may also, by regular automatic exchange or occasional automatic exchange, communicate to the competent authority of any other Member State concerned information received concerning the entry, exit, transit, storage and end-use of goods, including postal traffic, moved between the customs territory of the Community and other territories, and the presence and movement within the customs territory of the Community of non-community and end-use goods, where necessary to prevent or detect operations which constitute, or appear to constitute, breaches of customs or agricultural legislation.';

4. Article 18 shall be amended as follows:

(a) paragraph 1 shall be amended as follows:

(i) the first indent shall be replaced by the following:

'— when they have, or might have, ramifications in other Member States or in third countries, or';

(ii) the following subparagraph shall be added:

'Within six months of the receipt of the information conveyed by the Commission, the competent authorities of the Member States shall

forward to the Commission a summary of the anti-fraud measures taken by them on the basis of that information. The Commission shall, on the basis of those summaries, regularly prepare and convey to the Member States reports on the results of measures taken by the Member States.';

(b) the following paragraphs shall be added:

'7. Without prejudice to the provisions of the Community Customs Code relating to the establishment of a common framework for risk management, the data exchanged between the Commission and the Member States pursuant to Articles 17 and 18 may be stored and used for the purpose of strategic and operational analysis.

8. The Member States and the Commission may exchange the results of operational and strategic analyses carried out under this Regulation.';

5. in Title III, the following Articles shall be added:

'Article 18a

1. Without prejudice to the competences of the Member States, with a view to assisting the authorities referred to in Article 1(1) to detect movements of goods that are the object of operations in potential breach of customs and agricultural legislation and means of transport, including containers, used for that purpose, the Commission shall establish and manage a directory of data received from public or private service providers active in the international supply chain. That directory shall be directly accessible to those authorities.

2. In managing that directory, the Commission shall be empowered:

(a) to access or extract the contents of the data, by any means or in any form, and to reuse data in compliance with legislation applicable to intellectual property rights; the terms and procedures for data access or extraction shall be governed by a technical arrangement between the Commission, acting on behalf of the Community, and the service provider;

(b) to compare and contrast data that are accessible in or extracted from the directory, to index them, to enrich them from other data sources and to analyse them in compliance with Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (*);

(c) to make the data in this directory available using electronic data-processing techniques to the authorities referred to in Article 1(1).

3. The data referred to in this Article concern in particular movements of containers and/or means of transport and goods and persons concerned with those movements. Those shall include, where available, the following data:

(a) for movements of containers:

— container number,

— container loading status,

— date of movement,

— type of movement (loaded, unloaded, transhipped, entered, left, etc.),

— name of vessel or registration of means of transport,

— number of voyage/journey,

— place,

— freight bill or other transport document;

(b) for movements of means of transport:

— name of vessel or registration of means of transport,

— freight bill or other transport document,

— number of containers,

— weight of load,

— description and/or coding of goods,

— reservation number,

— seal number,

— place of first loading,

— place of final unloading,

— places of transhipment,

— expected date of arrival at place of final unloading;

(c) for persons involved in the movements to which points (a) and (b) apply: the name, maiden name, forenames, former surnames, aliases, date and place of birth, nationality, sex and address;

(d) for businesses involved in the movements to which points (a) and (b) apply: the business name, trading name, address of the business, registration number, VAT identification number and excise duties identification number and address of the owners, shippers, consignees, freight forwarders, carriers and other intermediaries or persons involved in the international supply chain.

4. Within the Commission, only designated analysts shall be empowered to process personal data to which paragraphs 2(b) and 2(c) apply.

Personal data which are not necessary for the purpose of achieving the aim in question shall be deleted immediately or have any identifying factors removed. In any event, they may be stored for no more than three years.

Article 18b

1. The Commission shall be authorised to provide training and all forms of assistance other than financial assistance for the liaison officers of third countries and of European and international organisations and agencies.

2. The Commission may make expertise, technical or logistical assistance, training or communication activity or any other operational support available to the Member States both for the achievement of the objectives of this Regulation and in the performance of Member States' duties in the framework of the implementation of the customs cooperation provided for by Articles 29 and 30 of the Treaty on European Union.

(*) OJ L 8, 12.1.2001, p. 1.';

6. Article 19 shall be replaced by the following:

'Article 19

Provided that the third country concerned has legally committed itself to providing the assistance necessary to assemble all the evidence of the irregular nature of operations which appear to be in breach of customs or agricultural legislation or to determine the extent of the operations which have been found to be in breach of such legislation, information obtained pursuant to this Regulation may be communicated to it:

— by the Commission or by the Member State concerned, subject, where appropriate, to the prior agreement of the competent authorities of the Member State which provided it, or

— by the Commission or the Member States concerned within the framework of a joint action if information is provided by more than one Member State, subject to the prior agreement of the competent authorities of the Member States which provided it.

Such communication by a Member State shall be made in compliance with its domestic provisions applicable to the transfer of personal data to third countries.

In all cases, it shall be ensured that the rules of the third country concerned offer a degree of protection equivalent to that provided for in Article 45(1) and (2).';

7. in Article 20(2), point (d) shall be deleted;

8. Article 23 shall be amended as follows:

(a) paragraph 2 shall be replaced by the following:

'2. The aim of the CIS, in accordance with the provisions of this Regulation, shall be to assist in preventing, investigating and prosecuting operations which are in breach of customs or agricultural legislation by making information available more rapidly and thereby increasing the effectiveness of the cooperation and control procedures of the competent authorities referred to in this Regulation.';

(b) in paragraph 3, the terms 'in Article K.1(8)' shall be replaced by the terms 'in Articles 29 and 30';

(c) in paragraph 4, the words 'the procedure set out in Article 43(2)' shall be replaced by the words 'the regulatory procedure with scrutiny referred to in Article 43(2)';

(d) paragraph 5 shall be deleted;

9. in Article 24, the following points shall be added:

'(g) goods detained, seized or confiscated;

(h) cash as defined in Article 2 of Regulation (EC) No 1889/2005 of the European Parliament and of the Council of 26 October 2005 on controls of cash entering or leaving the Community (*) detained, seized or confiscated.

(*) OJ L 309, 25.11.2005, p. 9.';

10. Article 25 shall be replaced by the following:

'*Article 25*

1. The items to be included in the CIS relating to each of the categories referred to in Article 24(a) to (h) shall be determined in accordance with the regulatory procedure with scrutiny referred to in Article 43(2) to the extent that this is necessary to achieve the aim of the System. Personal data may under no circumstances appear in the category referred to in Article 24(e).

2. With regard to the categories referred to in Article 24(a) to (d), the items of information to be included in respect of personal data shall comprise no more than:

(a) name, maiden name, forenames, former surnames and aliases;

(b) date and place of birth;

(c) nationality;

(d) sex;

(e) number and place and date of issue of the identity papers (passports, identity cards, driving licences);

(f) address;

(g) particular objective and permanent physical characteristics;

(h) a warning code indicating any history of being armed or violent or of having escaped;

(i) reason for inclusion of data;

(j) suggested action;

(k) registration number of the means of transport.

3. With regard to the category referred to in Article 24(f), the items of information to be included in respect of personal data shall comprise no more than the experts' names and forenames.

4. With regard to the categories referred to in Article 24(g) and (h), the items of information to be included in respect of personal data shall comprise no more than:

(a) name, maiden name, forenames, former surnames and aliases;

(b) date and place of birth;

(c) nationality;

(d) sex;

(e) address.

5. In all cases, no personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership and data concerning the health or sex life of an individual shall be included.';

11. Article 27 shall be replaced by the following:

'*Article 27*

1. Personal data which are included in the categories referred to in Article 24 shall be included in the CIS solely for the purposes of the following suggested actions:

(a) sighting and reporting;

(b) discreet surveillance;

(c) specific checks; and

(d) operational analysis.

2. Personal data which are included in the categories referred to in Article 24 may be included in the CIS only if, in particular on the basis of prior illegal activities or of information provided by way of assistance, there is a real indication that the person in question has carried out, is carrying out or is about to carry out operations in breach of customs or agricultural legislation which are of particular relevance at Community level.';

12. Article 34(3) shall be replaced by the following:

'3. To ensure the correct application of the data protection provisions of this Regulation, the Member States and the Commission shall regard the CIS as a personal data-processing system which is subject to:

— national provisions implementing Directive 95/46/EC,

— Regulation (EC) No 45/2001, and

— any more stringent provisions of this Regulation.';

13. Article 35 shall be replaced by the following:

'Article 35

1. Subject to Article 30(1), CIS partners shall be prohibited from using personal data from the CIS for any purpose other than that stated in Article 23(2).

2. Data may be duplicated only for technical purposes, provided that such duplication is required for the purpose of searches carried out by the authorities referred to in Article 29.

3. Personal data included in CIS by a Member State or the Commission may not be copied in data-processing systems for which the Member States or the Commission are responsible, except in systems of risk management used to direct national customs controls or in an operational analysis system used to coordinate actions at Community level.

In that case, only the analysts designated by the national authorities of each Member State and those designated by Commission services shall be empowered to process personal data obtained from the CIS within the framework respectively of a risk management system used to direct customs controls by national authorities or an operational analysis system used to coordinate actions at Community level.

Member States shall send the Commission a list of the risk management departments whose analysts are authorised to copy and process personal data entered in the CIS. The Commission shall inform the other Member States accordingly. It shall also provide all Member States with the corresponding information regarding its own services responsible for operational analysis.

The list of designated national authorities and Commission services shall be published for information by the Commission in the *Official Journal of the European Union*.

Personal data copied from the CIS shall be kept only for the time necessary to achieve the purpose for which they were copied. The need for their retention shall be reviewed at least annually by the copying CIS partner. The storage period shall not exceed 10 years. Personal data which are not necessary for the continuation of the analysis shall be deleted immediately or have any identifying factors removed.';

14. the second subparagraph of Article 36(2) shall be replaced by the following:

'In any event, access may be denied to any person whose data are processed during the period in which actions are carried out for the purposes of sighting and reporting or discreet surveillance and during the period in which the operational analysis of the data or administrative enquiry or criminal investigation is ongoing.';

15. Article 37 shall be amended as follows:

(a) paragraph 2 shall be replaced by the following:

'2. Any person may ask any national supervisory authority provided for in Article 28 of Directive 95/46/EC or the European Data Protection Supervisor provided for in Article 41(2) of Regulation (EC) No 45/2001 for access to the personal data concerning him in order to check that they are accurate and what use has been or is being made of them. This right shall be governed by the laws, regulations and procedures of the Member State in which the request is made or by Regulation (EC) No 45/2001, as the case may be. If the data were included by another Member State or by the Commission, the check shall be carried out in close cooperation with the national supervisory authority of that other Member State or with the European Data Protection Supervisor.';

(b) the following paragraph shall be inserted:

'3a. The European Data Protection Supervisor shall supervise compliance of the CIS with Regulation (EC) No 45/2001.';

(c) paragraph 4 shall be replaced by the following:

'4. The European Data Protection Supervisor shall convene a meeting at least once a year with all national data protection supervisory authorities competent for CIS-related supervisory issues.';

16. in Title V, the title of Chapter 7 shall be replaced by the following: 'Data security';

17. in Article 38(1), the following point shall be added:

'(c) by the Commission for the Community elements of the common communication network.';

18. the following Title shall be inserted:

'TITLE Va

CUSTOMS FILES IDENTIFICATION DATABASE

CHAPTER 1

Establishment of a customs files identification database

Article 41a

1. The CIS shall also include a specific database called the "Customs files identification database" (FIDE). Subject to the provisions of this Title, all the provisions of this Regulation relating to the CIS shall also apply to the FIDE, and any reference to the CIS shall include that database.

2. The objectives of the FIDE shall be to help to prevent operations in breach of customs legislation and of agricultural legislation applicable to goods entering or leaving the customs territory of the Community and to facilitate and accelerate their detection and prosecution.

3. The purpose of the FIDE shall be to allow the Commission, when it opens a coordination file within the meaning of Article 18 or prepares a Community mission in a third country within the meaning of Article 20, and the competent authorities of a Member State designated as regards administrative enquiries in accordance with Article 29, when they open an investigation file or investigate one or more persons or businesses, to identify the competent authorities of the other Member States or the Commission departments which are or have been investigating the persons or businesses concerned, in order to achieve the objectives specified in paragraph 2 by means of information on the existence of investigation files.

4. If the Member State or the Commission making a search in the FIDE needs fuller information on the registered investigation files on persons or businesses, it shall ask for the assistance of the supplier Member State.

5. The customs authorities of the Member States may use the FIDE within the framework of customs cooperation provided for in Articles 29 and 30 of the Treaty on European Union. In such a case, the Commission shall ensure the technical management of the database.

CHAPTER 2

Operation and use of the FIDE

Article 41b

1. The competent authorities may enter data from investigation files in the FIDE for the purposes defined in Article 41a(3) concerning cases which are in breach of customs legislation or agricultural legislation applicable to goods entering or leaving the customs territory of the Community and which are of particular relevance at Community level. The data shall cover only the following categories:

(a) persons and businesses which are or have been the subject of an administrative enquiry or a criminal investigation by the relevant service of a Member State, and

— are suspected of committing or of having committed a breach of customs or agriculture legislation or of participating in or of having participated in an operation in breach of such legislation,

— have been the subject of a finding relating to such an operation, or

— have been the subject of an administrative decision or an administrative penalty or judicial penalty for such an operation;

(b) the field concerned by the investigation file;

(c) the name, nationality and details of the relevant service in the Member State and the file number.

The data referred to in points (a), (b) and (c) shall be introduced separately for each person or business. The creation of links between those data shall be prohibited.

2. The personal data referred to in paragraph 1(a) shall consist only of the following:

(a) for persons: the name, maiden name, forename, former surnames and alias, date and place of birth, nationality and sex;

(b) for businesses: the business name, trading name, address of the business, VAT identification number and excise duties identification number.

3. Data shall be entered for a limited period in accordance with Article 41d.

Article 41c

1. The introduction and consultation of data in the FIDE shall be reserved exclusively to the authorities referred to in Article 41a.

2. Any consultation of the FIDE must specify the following personal data:

(a) for persons: the forename and/or name and/or maiden name and/or former surnames and/or alias and/or date of birth;

(b) for businesses: the business name and/or trading name and/or VAT identification number and/or excise duties identification number.

CHAPTER 3

Storage of data

Article 41d

1. The period for which data may be stored shall depend on the laws, regulations and procedures of the Member State supplying them. The following are the maximum periods, calculated from the date of entry of the data in the investigation file, which may not be exceeded:

(a) data concerning current investigation files may not be stored for more than three years without any operation in breach of customs and agricultural legislation being observed; data must be deleted before that time limit if one year has elapsed since the last observation;

(b) data concerning administrative enquiries or criminal investigations in which an operation in breach of customs and agricultural legislation has been established but which have not given rise to an administrative decision, a conviction or an order to pay a criminal fine or an administrative penalty may not be stored for more than six years;

(c) data concerning administrative enquiries or criminal investigations which have given rise to an administrative decision, a conviction or an order to pay a criminal fine or an administrative penalty may not be stored for more than 10 years.

These periods shall not be cumulative.

2. At all stages of an investigation file as referred to in paragraph 1(a), (b) and (c), as soon as a person to whom, or a business to which, Article 41b applies is cleared of suspicion under the laws, regulations and procedures of the supplier Member State, data concerning that person or business shall immediately be deleted.

3. The FIDE shall delete the data automatically as soon as the maximum storage period provided for in paragraph 1 has elapsed.';

19. Title VI shall be replaced by the following:

'TITLE VI

FINANCING

Article 42a

1. This Regulation is the basic act on which the financing of all Community action provided for herein is based, including:

(a) all costs of installing and maintaining the permanent technical infrastructure making available to the Member States the logistical, office automation and IT resources to coordinate joint customs operations, in particular special surveillance operations provided for in Article 7;

(b) the reimbursement of transport, accommodation and daily allowance costs of representatives of the Member States taking part in the Community missions provided for in Article 20, joint customs operations organised by or jointly with the Commission and training courses, ad hoc meetings and preparatory meetings for administrative investigations or operational actions conducted by the Member States, where they are organised by or jointly with the Commission.

Where the permanent technical infrastructure referred to in point (a) is used for the purposes of the customs cooperation provided for in Articles 29 and 30 of the Treaty on European Union, the transport, accommodation costs and the daily allowances of the representatives of the Member States shall be borne by the Member States;

(c) expenditure relating to the acquisition, study, development and maintenance of computer infrastructure (hardware), software and dedicated network connections, and to related production, support and training services for the purpose of carrying out the actions provided for in this Regulation, in particular preventing and combating fraud;

(d) expenditure relating to the provision of information and expenditure on related actions allowing access to information, data and data sources for the purpose of carrying out the actions provided for in this Regulation, in particular preventing and combating fraud;

(e) expenditure relating to use of the CIS provided for in instruments adopted under Articles 29 and 30 of the Treaty on European Union and in particular in the Convention on the use of information technology in

customs matters drawn up by the Council Act of 26 July 1995 (*), in so far as those instruments provide that that expenditure shall be borne by the general budget of the European Union.

2. Expenditure relating to the acquisition, study, development and maintenance of the Community components of the common communication network used for the purposes of paragraph 1(c) shall also be borne by the general budget of the European Union. The Commission shall conclude the necessary contracts on behalf of the Community to ensure the operational nature of those components.

3. Without prejudice to the expenses relating to the operation of the CIS and the amounts provided for by way of compensation pursuant to Article 40, the Member States and the Commission shall waive all claims for the reimbursement of expenditure relating to the supply of information or of documents or to the implementation of an administrative investigation or of any other operational action pursuant to this Regulation which are carried out at the request of a Member State or the Commission, except as regards the allowances, if any, paid to experts.

(*) OJ C 316, 27.11.1995, p. 33.';

20. Article 43 shall be amended as follows:

(a) paragraph 2 shall be replaced by the following:

'2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

(b) paragraph 3 shall be replaced by the following:

'3. The following measures, designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in paragraph 2:

(a) decisions on items to be included in the CIS as provided for in Article 25;

(b) determination of operations concerning the application of agricultural legislation in respect of which information is to be entered in the CIS, as provided for in Article 23(4).';

(c) paragraph 4 shall be replaced by the following:

'4. The committee shall examine all matters relating to the application of this Regulation which may be raised by its chairman, either on his own initiative or at the request of the representative of a Member State, in particular concerning:

— the general working of the mutual assistance arrangements provided for in this Regulation,

— the adoption of practical arrangements for forwarding the information referred to in Articles 15, 16 and 17,

— the information sent to the Commission pursuant to Articles 17 and 18 to ascertain if anything can be learnt from it, to decide on the measures required to put an end to practices found to be in breach of customs or agricultural legislation and, where appropriate, to suggest amendments to existing Community provisions or the drafting of additional ones,

— the organisation of joint customs operations, in particular special surveillance operations provided for in Article 7,

— the preparation of investigations carried out by the Member States and coordinated by the Commission and Community missions as provided for in Article 20,

— measures taken to safeguard the confidentiality of information, in particular personal data, exchanged under this Regulation, other than that provided for in Title V,

— the implementation and proper operation of the CIS and all the technical and operational measures required to ensure the security of the system,

— the need to store information in the CIS,

— the measures taken to safeguard the confidentiality of information entered in the CIS under this Regulation, particularly personal data, and to ensure compliance with the obligations of those responsible for processing,

— the measures adopted pursuant to Article 38(2).';

(d) paragraph 5 shall be replaced by the following:

'5. The committee shall examine all problems with the operation of the CIS which are encountered by the national supervisory authorities referred to in Article 37. The committee shall meet in its ad hoc formation at least once a year.';

21. in Articles 44 and 45(2), the terms 'in Title V on the CIS' shall be replaced by the terms 'in Titles V and Va';

22. the following Article shall be inserted:

'Article 51a

The Commission, in cooperation with the Member States, shall report each year to the European Parliament and to the Council on the measures taken in implementation of this Regulation.';

23. Article 53 shall be amended as follows:

(a) the numbering of paragraph 1 shall be deleted;

(b) paragraph 2 shall be deleted.

Article 2

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 9 July 2008.

For the European Parliament	*For the Council*
The President	*The President*
H.-G. PÖTTERING	J.-P. JOUYET

REGULATION (EC) No 767/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 July 2008

concerning the Visa Information System (VIS) and the exchange of data between Member States on short-stay visas (VIS Regulation)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 62(2)(b)(ii) and Article 66 thereof,

Having regard to the proposal from the Commission,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ([1]),

Whereas:

(1) Building upon the conclusions of the Council of 20 September 2001, and the conclusions of the European Council in Laeken in December 2001, in Seville in June 2002, in Thessaloniki in June 2003 and in Brussels in March 2004, the establishment of the Visa Information System (VIS) represents one of the key initiatives within the policies of the European Union aimed at establishing an area of freedom, security and justice.

(2) Council Decision 2004/512/EC of 8 June 2004 establishing the Visa Information System (VIS) ([2]) established the VIS as a system for the exchange of visa data between Member States.

(3) It is now necessary to define the purpose, the functionalities and responsibilities for the VIS, and to establish the conditions and procedures for the exchange of visa data between Member States to facilitate the examination of visa applications and related decisions, taking into account the orientations for the development of the VIS adopted by the Council on 19 February 2004 and to give the Commission the mandate to set up the VIS.

(4) For a transitional period, the Commission should be responsible for the operational management of the central VIS, of the national interfaces and of certain aspects of the communication infrastructure between the central VIS and the national interfaces. In the long term, and following an impact assessment containing a substantive analysis of alternatives from a financial, operational and organisational perspective, and legislative proposals from the Commission, a permanent Management Authority with responsibility for these tasks should be established. The transitional period should last for no more than five years from the date of entry into force of this Regulation.

(5) The VIS should have the purpose of improving the implementation of the common visa policy, consular cooperation and consultation between central visa authorities by facilitating the exchange of data between Member States on applications and on the decisions relating thereto, in order to facilitate the visa application procedure, to prevent 'visa shopping', to facilitate the fight against fraud and to facilitate checks at external border crossing points and within the territory of the Member States. The VIS should also assist in the identification of any person who may not, or may no longer, fulfil the conditions for entry to, stay or residence on the territory of the Member States, and facilitate the application of Council Regulation (EC) No 343/2003 of 18 February 2003 establishing the criteria and mechanism for determining the Member State responsible for examining an asylum application lodged in one of the Member States by a third-country national ([3]), and contribute to the prevention of threats to the internal security of any of the Member States.

(6) This Regulation is based on the *acquis* of the common visa policy. The data to be processed by the VIS should be determined on the basis of the data provided by the common form for visa applications as introduced by Council Decision 2002/354/EC of 25 April 2002 on the adaptation of Part III of, and the creation of an Annex 16 to, the Common Consular Instructions ([4]), and the information on the visa sticker provided for in Council Regulation (EC) No 1683/95 of 29 May 1995 laying down a uniform format for visas ([5]).

(7) The VIS should be connected to the national systems of the Member States to enable the competent authorities of the Member States to process data on visa applications and on visas issued, refused, annulled, revoked or extended.

([1]) Opinion of the European Parliament of 7 June 2007 (OJ C 125 E, 22.5.2008, p. 118) and Council Decision of 23 June 2008.

([2]) OJ L 213, 15.6.2004, p. 5.

([3]) OJ L 50, 25.2.2003, p. 1.

([4]) OJ L 123, 9.5.2002, p. 50.

([5]) OJ L 164, 14.7.1995, p. 1. Regulation as last amended by Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

(8) The conditions and procedures for entering, amending, deleting and consulting the data in the VIS should take into account the procedures laid down in the Common Consular Instructions on visas for the diplomatic missions and consular posts ([1]) (the Common Consular Instructions).

(9) The technical functionalities of the network for consulting the central visa authorities as laid down in Article 17(2) of the Convention implementing the Schengen Agreement of 14 June 1985 between the Governments of the States of the Benelux Economic Union, the Federal Republic of Germany and the French Republic on the gradual abolition of checks at their common borders ([2]) (the Schengen Convention) should be integrated into the VIS.

(10) To ensure reliable verification and identification of visa applicants, it is necessary to process biometric data in the VIS.

(11) It is necessary to define the competent authorities of the Member States, the duly authorised staff of which are to have access to enter, amend, delete or consult data for the specific purposes of the VIS in accordance with this Regulation to the extent necessary for the performance of their tasks.

(12) Any processing of VIS data should be proportionate to the objectives pursued and necessary for the performance of the tasks of the competent authorities. When using the VIS, the competent authorities should ensure that the human dignity and integrity of the persons whose data are requested are respected and should not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation.

(13) This Regulation should be complemented by a separate legal instrument adopted under Title VI of the Treaty on European Union concerning access for the consultation of the VIS by authorities responsible for internal security.

(14) The personal data stored in the VIS should be kept for no longer than is necessary for the purposes of the VIS. It is appropriate to keep the data for a maximum period of five years, in order to enable data on previous applications to be taken into account for the assessment of visa applications, including the applicants' good faith, and for the documentation of illegal immigrants who may, at some stage, have applied for a visa. A shorter period would not be sufficient for those purposes. The data should be deleted after a period of five years, unless there are grounds to delete them earlier.

(15) Precise rules should be laid down as regards the responsibilities for the establishment and operation of the VIS, and the responsibilities of the Member States for the national systems and the access to data by the national authorities.

(16) Rules on the liability of the Member States in respect of damage arising from any breach of this Regulation should be laid down. The liability of the Commission in respect of such damage is governed by the second paragraph of Article 288 of the Treaty.

(17) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ([3]) applies to the processing of personal data by the Member States in application of this Regulation. However, certain points should be clarified in respect of the responsibility for the processing of data, of safeguarding the rights of the data subjects and of the supervision on data protection.

(18) Regulation (EC) No 45/2001 of the European Parliament and the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data ([4]) applies to the activities of the Community institutions or bodies when carrying out their tasks as responsible for the operational management of the VIS. However, certain points should be clarified in respect of the responsibility for the processing of data and of the supervision of data protection.

(19) The National Supervisory Authorities established in accordance with Article 28 of Directive 95/46/EC should monitor the lawfulness of the processing of personal data by the Member States, while the European Data Protection Supervisor as established by Regulation (EC) No 45/2001 should monitor the activities of the Community institutions and bodies in relation to the processing of personal data, taking into account the limited tasks of the Community institutions and bodies with regard to the data themselves.

([1]) OJ C 326, 22.12.2005, p. 1. Instructions as last amended by Council Decision 2006/684/EC (OJ L 280, 12.10.2006, p. 29).

([2]) OJ L 239, 22.9.2000, p. 19. Convention as last amended by Regulation (EC) No 1987/2006 of the European Parliament and of the Council (OJ L 381, 28.12.2006, p. 4).

([3]) OJ L 281, 23.11.1995, p. 31. Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

([4]) OJ L 8, 12.1.2001, p. 1.

(20) The European Data Protection Supervisor and the National Supervisory Authorities should cooperate actively with each other.

(21) The effective monitoring of the application of this Regulation requires evaluation at regular intervals.

(22) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented.

(23) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([1]).

(24) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union.

(25) Since the objectives of this Regulation, namely the establishment of a common Visa Information System and the creation of common obligations, conditions and procedures for the exchange of visa data between Member States, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale and impact of the action, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(26) In accordance with Articles 1 and 2 of the Protocol on the position of Denmark, annexed to the Treaty on European Union and the Treaty establishing the European Community, Denmark does not take part in the adoption of this Regulation and is therefore not bound by it or subject to its application. Given that this Regulation builds upon the Schengen *acquis* under the provisions of Title IV of Part Three of the Treaty establishing the European Community, Denmark should, in accordance with Article 5 of that Protocol, decide within a period of six months after the adoption of this Regulation whether it will implement it in its national law.

(27) As regards Iceland and Norway, this Regulation constitutes a development of provisions of the Schengen *acquis* within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen *acquis* ([2]), which falls within the area referred to in Article 1, point B of Council Decision 1999/437/EC ([3]) of 17 May 1999 on certain arrangements for the application of that Agreement.

(28) An arrangement should be made to allow representatives of Iceland and Norway to be associated with the work of committees assisting the Commission in the exercise of its implementing powers. Such an arrangement has been contemplated in the Agreement in the form of Exchange of Letters between the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning committees which assist the European Commission in the exercise of its executive powers ([4]), annexed to the Agreement referred to in Recital 27.

(29) This Regulation constitutes a development of provisions of the Schengen *acquis* in which the United Kingdom does not take part, in accordance with Council Decision 2000/365/EC of 29 May 2000 concerning the request of the United Kingdom of Great Britain and Northern Ireland to take part in some of the provisions of the Schengen *acquis* ([5]), and subsequent Council Decision 2004/926/EC of 22 December 2004 on the putting into effect of parts of the Schengen *acquis* by the United Kingdom of Great Britain and Northern Ireland ([6]). The United Kingdom is therefore not taking part in its adoption and is not bound by it or subject to its application.

(30) This Regulation constitutes a development of provisions of the Schengen *acquis* in which Ireland does not take part, in accordance with Council Decision 2002/192/EC of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* ([7]). Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application.

(31) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Agreement signed by the European Union, the European Community and the Swiss Confederation on the association of the Swiss Confederation with the implementation, application and development

([1]) OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

([2]) OJ L 176, 10.7.1999, p. 36.
([3]) OJ L 176, 10.7.1999, p. 31.
([4]) OJ L 176, 10.7.1999, p. 53.
([5]) OJ L 131, 1.6.2000, p. 43.
([6]) OJ L 395, 31.12.2004, p. 70.
([7]) OJ L 64, 7.3.2002, p. 20.

of the Schengen *acquis* which falls within the area referred to in Article 1, point B of Decision 1999/437/EC read in conjunction with Article 4(1) of Council Decision 2004/860/EC [1].

(32) An arrangement should be made to allow representatives of Switzerland to be associated with the work of committees assisting the Commission in the exercise of its implementing powers. Such an arrangement has been contemplated in the Exchange of Letters between the Community and Switzerland, annexed to the Agreement referred to in Recital 31.

(33) This Regulation constitutes an act building on the Schengen *acquis* or otherwise related to it within the meaning of Article 3(2) of the 2003 Act of Accession and Article 4(2) of the 2005 Act of Accession,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

This Regulation defines the purpose of, the functionalities of and the responsibilities for the Visa Information System (VIS), as established by Article 1 of Decision 2004/512/EC. It sets up the conditions and procedures for the exchange of data between Member States on applications for short-stay visas and on the decisions taken in relation thereto, including the decision whether to annul, revoke or extend the visa, to facilitate the examination of such applications and the related decisions.

Article 2

Purpose

The VIS shall have the purpose of improving the implementation of the common visa policy, consular cooperation and consultation between central visa authorities by facilitating the exchange of data between Member States on applications and on the decisions relating thereto, in order:

(a) to facilitate the visa application procedure;

(b) to prevent the bypassing of the criteria for the determination of the Member State responsible for examining the application;

(c) to facilitate the fight against fraud;

(d) to facilitate checks at external border crossing points and within the territory of the Member States;

(e) to assist in the identification of any person who may not, or may no longer, fulfil the conditions for entry to, stay or residence on the territory of the Member States;

(f) to facilitate the application of Regulation (EC) No 343/2003;

(g) to contribute to the prevention of threats to the internal security of any of the Member States.

Article 3

Availability of data for the prevention, detection and investigation of terrorist offences and other serious criminal offences

1. The designated authorities of the Member States may in a specific case and following a reasoned written or electronic request access the data kept in the VIS referred to in Articles 9 to 14 if there are reasonable grounds to consider that consultation of VIS data will substantially contribute to the prevention, detection or investigation of terrorist offences and of other serious criminal offences. Europol may access the VIS within the limits of its mandate and when necessary for the performance of its tasks.

2. The consultation referred to in paragraph 1 shall be carried out through central access point(s) which shall be responsible for ensuring strict compliance with the conditions for access and the procedures established in Council Decision 2008/633/JHA of 23 June 2008 concerning access for consultation of the Visa Information System (VIS) by the designated authorities of Member States and by Europol for the purposes of the prevention, detection and investigation of terrorist offences and of other serious criminal offences [2]. Member States may designate more than one central access point to reflect their organisational and administrative structure in fulfilment of their constitutional or legal requirements. In an exceptional case of urgency, the central access point(s) may receive written, electronic or oral requests and only verify *ex-post* whether all the conditions for access are fulfilled, including whether an exceptional case of urgency existed. The *ex-post* verification shall take place without undue delay after the processing of the request.

3. Data obtained from the VIS pursuant to the Decision referred to in paragraph 2 shall not be transferred or made available to a third country or to an international organisation.

[1] Decision 2004/860/EC of 25 October 2004 on the signing, on behalf of the European Community, and on the provisional application of certain provisions of the Agreement between the European Union, the European Community and the Swiss Confederation, concerning the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* (OJ L 370, 17.12.2004, p. 78).

[2] See page 129 of this Official Journal.

However, in an exceptional case of urgency, such data may be transferred or made available to a third country or an international organisation exclusively for the purposes of the prevention and detection of terrorist offences and of other serious criminal offences and under the conditions set out in that Decision. In accordance with national law, Member States shall ensure that records on such transfers are kept and make them available to national data protection authorities on request. The transfer of data by the Member State which entered the data in the VIS shall be subject to the national law of that Member State.

4. This Regulation is without prejudice to any obligations under applicable national law for the communication of information on any criminal activity detected by the authorities referred to in Article 6 in the course of their duties to the responsible authorities for the purposes of preventing, investigating and prosecuting the related criminal offences.

Article 4

Definitions

For the purposes of this Regulation, the following definitions shall apply:

1. 'visa' means:

   (a) 'short-stay visa' as defined in Article 11(1)(a) of the Schengen Convention;

   (b) 'transit visa' as defined in Article 11(1)(b) of the Schengen Convention;

   (c) 'airport transit visa' as defined in part I, point 2.1.1, of the Common Consular Instructions;

   (d) 'visa with limited territorial validity' as defined in Articles 11(2), 14 and 16 of the Schengen Convention;

   (e) 'national long-stay visa valid concurrently as a short-stay visa' as defined in Article 18 of the Schengen Convention;

2. 'visa sticker' means the uniform format for visas as defined by Regulation (EC) No 1683/95;

3. 'visa authorities' means the authorities which in each Member State are responsible for examining and for taking decisions on visa applications or for decisions whether to annul, revoke or extend visas, including the central visa authorities and the authorities responsible for issuing visas at the border in accordance with Council Regulation (EC) No 415/2003 of 27 February 2003 on the issue of visas at the border, including the issue of such visas to seamen in transit ([1]);

4. 'application form' means the uniform application form for visas in Annex 16 to the Common Consular Instructions;

5. 'applicant' means any person subject to the visa requirement pursuant to Council Regulation (EC) No 539/2001 of 15 March 2001 listing the third countries whose nationals must be in possession of visas when crossing the external borders and those whose nationals are exempt from that requirement ([2]), who has lodged an application for a visa;

6. 'group members' means applicants who are obliged for legal reasons to enter and leave the territory of the Member States together;

7. 'travel document' means a passport or other equivalent document entitling the holder to cross the external borders and to which a visa may be affixed;

8. 'Member State responsible' means the Member State which has entered the data in the VIS;

9. 'verification' means the process of comparison of sets of data to establish the validity of a claimed identity (one-to-one check);

10. 'identification' means the process of determining a person's identity through a database search against multiple sets of data (one-to-many check);

11. 'alphanumeric data' means data represented by letters, digits, special characters, spaces and punctuation marks.

Article 5

Categories of data

1. Only the following categories of data shall be recorded in the VIS:

(a) alphanumeric data on the applicant and on visas requested, issued, refused, annulled, revoked or extended referred to in Articles 9(1) to (4) and Articles 10 to 14;

([1]) OJ L 64, 7.3.2003, p. 1.

([2]) OJ L 81, 21.3.2001, p. 1. Regulation as last amended by Regulation (EC) No 1932/2006 (OJ L 405, 30.12.2006, p. 23).

(b) photographs referred to in Article 9(5);

(c) fingerprint data referred to in Article 9(6);

(d) links to other applications referred to in Article 8(3) and (4).

2. The messages transmitted by the infrastructure of the VIS, referred to in Article 16, Article 24(2) and Article 25(2), shall not be recorded in the VIS, without prejudice to the recording of data processing operations pursuant to Article 34.

Article 6

Access for entering, amending, deleting and consulting data

1. Access to the VIS for entering, amending or deleting the data referred to in Article 5(1) in accordance with this Regulation shall be reserved exclusively to the duly authorised staff of the visa authorities.

2. Access to the VIS for consulting the data shall be reserved exclusively to the duly authorised staff of the authorities of each Member State which are competent for the purposes laid down in Articles 15 to 22, limited to the extent that the data are required for the performance of their tasks in accordance with those purposes, and proportionate to the objectives pursued.

3. Each Member State shall designate the competent authorities, the duly authorised staff of which shall have access to enter, amend, delete or consult data in the VIS. Each Member State shall without delay communicate to the Commission a list of these authorities, including those referred to in Article 41(4), and any amendments thereto. That list shall specify for what purpose each authority may process data in the VIS.

Within 3 months after the VIS has become operational in accordance with Article 48(1), the Commission shall publish a consolidated list in the *Official Journal of the European Union*. Where there are amendments thereto, the Commission shall publish once a year an updated consolidated list.

Article 7

General principles

1. Each competent authority authorised to access the VIS in accordance with this Regulation shall ensure that the use of the VIS is necessary, appropriate and proportionate to the performance of the tasks of the competent authorities.

2. Each competent authority shall ensure that in using the VIS, it does not discriminate against applicants and visa holders on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation and that it fully respects the human dignity and the integrity of the applicant or of the visa holder.

CHAPTER II

ENTRY AND USE OF DATA BY VISA AUTHORITIES

Article 8

Procedures for entering data upon the application

1. On receipt of an application, the visa authority shall create without delay the application file, by entering the data referred to in Article 9 in the VIS, as far as these data are required to be provided by the applicant.

2. When creating the application file, the visa authority shall check in the VIS, in accordance with Article 15, whether a previous application of the individual applicant has been registered in the VIS by any of the Member States.

3. If a previous application has been registered, the visa authority shall link each new application file to the previous application file on that applicant.

4. If the applicant is travelling in a group or with his spouse and/or children, the visa authority shall create an application file for each applicant and link the application files of the persons travelling together.

5. Where particular data are not required to be provided for legal reasons or factually cannot be provided, the specific data field(s) shall be marked as 'not applicable'. In the case of fingerprints, the system shall for the purposes of Article 17 permit a distinction to be made between the cases where fingerprints are not required to be provided for legal reasons and the cases where they cannot be provided factually; after a period of four years this functionality shall expire unless it is confirmed by a Commission decision on the basis of the evaluation referred to in Article 50(4).

Article 9

Data upon lodging the application

The visa authority shall enter the following data in the application file:

1. the application number;

2. status information, indicating that a visa has been requested;

3. the authority with which the application has been lodged, including its location, and whether the application has been lodged with that authority representing another Member State;

4. the following data to be taken from the application form:

   (a) surname, surname at birth (former surname(s)); first name(s); sex; date, place and country of birth;

   (b) current nationality and nationality at birth;

   (c) type and number of the travel document, the authority which issued it and the date of issue and of expiry;

   (d) place and date of the application;

   (e) type of visa requested;

   (f) details of the person issuing an invitation and/or liable to pay the applicant's subsistence costs during the stay, being:

      (i) in the case of a natural person, the surname and first name and address of the person;

      (ii) in the case of a company or other organisation, the name and address of the company/other organisation, surname and first name of the contact person in that company/organisation;

   (g) main destination and duration of the intended stay;

   (h) purpose of travel;

   (i) intended date of arrival and departure;

   (j) intended border of first entry or transit route;

   (k) residence;

   (l) current occupation and employer; for students: name of school;

   (m) in the case of minors, surname and first name(s) of the applicant's father and mother;

5. a photograph of the applicant, in accordance with Regulation (EC) No 1683/95;

6. fingerprints of the applicant, in accordance with the relevant provisions of the Common Consular Instructions.

Article 10

Data to be added for a visa issued

1. Where a decision has been taken to issue a visa, the visa authority that issued the visa shall add the following data to the application file:

   (a) status information indicating that the visa has been issued;

   (b) the authority that issued the visa, including its location, and whether that authority issued it on behalf of another Member State;

   (c) place and date of the decision to issue the visa;

   (d) the type of visa;

   (e) the number of the visa sticker;

   (f) the territory in which the visa holder is entitled to travel, in accordance with the relevant provisions of the Common Consular Instructions;

   (g) the commencement and expiry dates of the validity period of the visa;

   (h) the number of entries authorised by the visa in the territory for which the visa is valid;

   (i) the duration of the stay as authorised by the visa;

   (j) if applicable, the information indicating that the visa has been issued on a separate sheet in accordance with Council Regulation (EC) No 333/2002 of 18 February 2002 on a uniform format for forms for affixing the visa issued by Member States to persons holding travel documents not recognised by the Member State drawing up the form [1].

2. If an application is withdrawn or not pursued further by the applicant before a decision has been taken whether to issue a visa, the visa authority with which the application was lodged shall indicate that the application has been closed for these reasons and the date when the application was closed.

[1] OJ L 53, 23.2.2002, p. 4.

Article 11

Data to be added where the examination of the application is discontinued

In circumstances where the visa authority representing another Member State is forced to discontinue the examination of the application, it shall add the following data to the application file:

1. status information indicating that the examination of the application has been discontinued;

2. the authority that discontinued the examination of the application, including its location;

3. place and date of the decision to discontinue the examination;

4. the Member State competent to examine the application.

Article 12

Data to be added for a visa refusal

1. Where a decision has been taken to refuse a visa, the visa authority which refused the visa shall add the following data to the application file:

(a) status information indicating that the visa has been refused;

(b) the authority that refused the visa, including its location;

(c) place and date of the decision to refuse the visa.

2. The application file shall also indicate the ground(s) for refusal of the visa, which shall be one or more of the following. The applicant:

(a) has no valid travel document(s);

(b) has a false/counterfeit/forged travel document;

(c) does not justify the purpose and conditions of stay, in particular is considered to represent a specific risk of illegal immigration pursuant to Part V of the Common Consular Instructions;

(d) has already stayed for three months during a six-month period on the territory of the Member States;

(e) does not have sufficient means of subsistence in relation to the period and form of stay, or the means to return to the country of origin or transit;

(f) is a person for whom an alert has been issued for the purposes of refusing entry in the Schengen Information System (SIS) and/or in the national register;

(g) is considered to constitute a threat to public policy, internal security or the international relations of any of the Member States, or to public health, as defined in Article 2 point 19 of Regulation (EC) No 562/2006 of the European Parliament and of the Council of 15 March 2006 establishing a Community Code on the rules governing the movement of persons across borders (Schengen Borders Code) ([1]).

Article 13

Data to be added for a visa annulled or revoked or with a shortened validity period

1. Where a decision has been taken to annul or to revoke a visa, or to shorten the validity period of a visa, the visa authority that has taken the decision shall add the following data to the application file:

(a) status information indicating that the visa has been annulled or revoked or the validity period has been shortened;

(b) authority that annulled or revoked the visa or shortened the validity period of the visa, including its location;

(c) place and date of the decision;

(d) the new expiry date of the validity of the visa, if appropriate;

(e) the number of the visa sticker, if the reduced period takes the form of a new visa sticker.

2. The application file shall also indicate the ground(s) for annulment, revocation or shortening the validity period of the visa, which shall be:

(a) in the case of annulment or revocation, one or more of the grounds listed in Article 12(2);

([1]) OJ L 105, 13.4.2006, p. 1. Regulation as amended by Regulation (EC) No 296/2008 (OJ L 97, 9.4.2008, p. 60).

(b) in the case of a decision to shorten the validity period of the visa, one or more of the following grounds:

(i) for the purposes of the expulsion of the visa holder;

(ii) absence of adequate means of subsistence for the initially intended duration of the stay.

Article 14

Data to be added for a visa extended

1. Where a decision has been taken to extend a visa, the visa authority which extended the visa shall add the following data to the application file:

(a) status information indicating that the visa has been extended;

(b) the authority that extended the visa, including its location;

(c) place and date of the decision;

(d) the number of the visa sticker, if the extension of the visa takes the form of a new visa;

(e) the commencement and expiry dates of the extended period;

(f) period of the extension of the authorised duration of the stay;

(g) the territory in which the visa holder is entitled to travel, in accordance with the relevant provisions of the Common Consular Instructions;

(h) the type of the visa extended.

2. The application file shall also indicate the grounds for extending the visa, which shall be one or more of the following:

(a) force majeure;

(b) humanitarian reasons;

(c) serious occupational reasons;

(d) serious personal reasons.

Article 15

Use of the VIS for examining applications

1. The competent visa authority shall consult the VIS for the purposes of the examination of applications and the decisions relating to those applications, including the decision whether to annul, revoke, extend or shorten the validity of the visa in accordance with the relevant provisions.

2. For the purposes referred to in paragraph 1, the competent visa authority shall be given access to search with one or several of the following data:

(a) the application number;

(b) the data referred to in Article 9(4)(a);

(c) the data on the travel document, referred to in Article 9(4)(c);

(d) the surname, first name and address of the natural person or the name and address of the company/other organisation, referred to in Article 9(4)(f);

(e) fingerprints;

(f) the number of the visa sticker and date of issue of any previous visa.

3. If the search with one or several of the data listed in paragraph 2 indicates that data on the applicant are recorded in the VIS, the competent visa authority shall be given access to the application file(s) and the linked application file(s) pursuant to Article 8(3) and (4), solely for the purposes referred to in paragraph 1.

Article 16

Use of the VIS for consultation and requests for documents

1. For the purposes of consultation between central visa authorities on applications according to Article 17(2) of the Schengen Convention, the consultation request and the responses thereto shall be transmitted in accordance with paragraph 2 of this Article.

2. The Member State which is responsible for examining the application shall transmit the consultation request with the application number to the VIS, indicating the Member State or the Member States to be consulted.

The VIS shall transmit the request to the Member State or the Member States indicated.

The Member State or the Member States consulted shall transmit their response to the VIS, which shall transmit that response to the Member State which initiated the request.

3. The procedure set out in paragraph 2 may also apply to the transmission of information on the issue of visas with limited territorial validity and other messages related to consular

cooperation as well as to the transmission of requests to the competent visa authority to forward copies of travel documents and other documents supporting the application and to the transmission of electronic copies of those documents. The competent visa authorities shall respond to the request without delay.

4. The personal data transmitted pursuant to this Article shall be used solely for the consultation of central visa authorities and consular cooperation.

Article 17

Use of data for reporting and statistics

The competent visa authorities shall have access to consult the following data, solely for the purposes of reporting and statistics without allowing the identification of individual applicants:

1. status information;

2. the competent visa authority, including its location;

3. current nationality of the applicant;

4. border of first entry;

5. date and place of the application or the decision concerning the visa;

6. the type of visa requested or issued;

7. the type of the travel document;

8. the grounds indicated for any decision concerning the visa or visa application;

9. the competent visa authority, including its location, which refused the visa application and the date of the refusal;

10. the cases in which the same applicant applied for a visa from more than one visa authority, indicating these visa authorities, their location and the dates of refusals;

11. purpose of travel;

12. the cases in which the data referred to in Article 9(6) could factually not be provided, in accordance with the second sentence of Article 8(5);

13. the cases in which the data referred to in Article 9(6) was not required to be provided for legal reasons, in accordance with the second sentence of Article 8(5);

14. the cases in which a person who could factually not provide the data referred to in Article 9(6) was refused a visa, in accordance with the second sentence of Article 8(5).

CHAPTER III

ACCESS TO DATA BY OTHER AUTHORITIES

Article 18

Access to data for verification at external border crossing points

1. For the sole purpose of verifying the identity of the visa holder and/or the authenticity of the visa and/or whether the conditions for entry to the territory of the Member States in accordance with Article 5 of the Schengen Borders Code are fulfilled, the competent authorities for carrying out checks at external border crossing points in accordance with the Schengen Borders Code shall, subject to paragraphs 2 and 3, have access to search using the number of the visa sticker in combination with verification of fingerprints of the visa holder.

2. For a maximum period of three years after the VIS has started operations, the search may be carried out using only the number of the visa sticker. As from one year after the start of operations, the period of three years may be reduced in the case of air borders in accordance with the procedure referred to in Article 49(3).

3. For visa holders whose fingerprints cannot be used, the search shall be carried out only with the number of the visa sticker.

4. If the search with the data listed in paragraph 1 indicates that data on the visa holder are recorded in the VIS, the competent border control authority shall be given access to consult the following data of the application file as well as of linked application file(s) pursuant to Article 8(4), solely for the purposes referred to in paragraph 1:

(a) the status information and the data taken from the application form, referred to in Article 9(2) and (4);

(b) photographs;

(c) the data entered in respect of the visa(s) issued, annulled, revoked or whose validity is extended or shortened, referred to in Articles 10, 13 and 14.

5. In circumstances where verification of the visa holder or of the visa fails or where there are doubts as to the identity of the visa holder, the authenticity of the visa and/or the travel document, the duly authorised staff of those competent authorities shall have access to data in accordance with Article 20(1) and (2).

Article 19

Access to data for verification within the territory of the Member States

1. For the sole purpose of verifying the identity of the visa holder and/or the authenticity of the visa and/or whether the conditions for entry to, stay or residence on the territory of the Member States are fulfilled, the authorities competent for carrying out checks within the territory of the Member States as to whether the conditions for entry to, stay or residence on the territory of the Member States are fulfilled, shall have access to search with the number of the visa sticker in combination with verification of fingerprints of the visa holder, or the number of the visa sticker.

For visa holders whose fingerprints cannot be used, the search shall be carried out only with the number of the visa sticker.

2. If the search with the data listed in paragraph 1 indicates that data on the visa holder are recorded in the VIS, the competent authority shall be given access to consult the following data of the application file as well as of linked application file(s) pursuant to Article 8(4), solely for the purposes referred to in paragraph 1:

(a) the status information and the data taken from the application form, referred to in Article 9(2) and (4);

(b) photographs;

(c) the data entered in respect of the visa(s) issued, annulled, revoked or whose validity is extended or shortened, referred to in Articles 10, 13 and 14.

3. In circumstances where verification of the visa holder or of the visa fails or where there are doubts as to the identity of the visa holder, the authenticity of the visa and/or the travel document, the duly authorised staff of the competent authorities shall have access to data in accordance with Article 20(1) and (2).

Article 20

Access to data for identification

1. Solely for the purpose of the identification of any person who may not, or may no longer, fulfil the conditions for the entry to, stay or residence on the territory of the Member States, the authorities competent for carrying out checks at external border crossing points in accordance with the Schengen Borders Code or within the territory of the Member States as to whether the conditions for entry to, stay or residence on the territory of the Member States are fulfilled, shall have access to search with the fingerprints of that person.

Where the fingerprints of that person cannot be used or the search with the fingerprints fails, the search shall be carried out with the data referred to in Article 9(4)(a) and/or (c); this search may be carried out in combination with the data referred to in Article 9(4)(b).

2. If the search with the data listed in paragraph 1 indicates that data on the applicant are recorded in the VIS, the competent authority shall be given access to consult the following data of the application file and the linked application file(s), pursuant to Article 8(3) and (4), solely for the purposes referred to in paragraph 1:

(a) the application number, the status information and the authority to which the application was lodged;

(b) the data taken from the application form, referred to in Article 9(4);

(c) photographs;

(d) the data entered in respect of any visa issued, refused, annulled, revoked or whose validity is extended or shortened, or of applications where examination has been discontinued, referred to in Articles 10 to 14.

3. Where the person holds a visa, the competent authorities shall access the VIS first in accordance with Articles 18 or 19.

Article 21

Access to data for determining the responsibility for asylum applications

1. For the sole purpose of determining the Member State responsible for examining an asylum application according to Articles 9 and 21 of Regulation (EC) No 343/2003, the competent asylum authorities shall have access to search with the fingerprints of the asylum seeker.

Where the fingerprints of the asylum seeker cannot be used or the search with the fingerprints fails, the search shall be carried out with the data referred to in Article 9(4)(a) and/or (c); this search may be carried out in combination with the data referred to in Article 9(4)(b).

2. If the search with the data listed in paragraph 1 indicates that a visa issued with an expiry date of no more than six months before the date of the asylum application, and/or a visa extended to an expiry date of no more than six months before the date of the asylum application, is recorded in the VIS, the competent asylum authority shall be given access to consult the following data of the application file, and as regards the data listed in point (g) of the spouse and children, pursuant to Article 8(4), for the sole purpose referred to in paragraph 1:

(a) the application number and the authority that issued or extended the visa, and whether the authority issued it on behalf of another Member State;

(b) the data taken from the application form referred to in Article 9(4)(a) and (b);

(c) the type of visa;

(d) the period of validity of the visa;

(e) the duration of the intended stay;

(f) photographs;

(g) the data referred to in Article 9(4)(a) and (b) of the linked application file(s) on the spouse and children.

3. The consultation of the VIS pursuant to paragraphs 1 and 2 of this Article shall be carried out only by the designated national authorities referred to in Article 21(6) of Regulation (EC) No 343/2003.

Article 22

Access to data for examining the application for asylum

1. For the sole purpose of examining an application for asylum, the competent asylum authorities shall have access in accordance with Article 21 of Regulation (EC) No 343/2003 to search with the fingerprints of the asylum seeker.

Where the fingerprints of the asylum seeker cannot be used or the search with the fingerprints fails, the search shall be carried out with the data referred to in Article 9(4)(a) and/or (c); this search may be carried out in combination with the data referred to in Article 9(4)(b).

2. If the search with the data listed in paragraph 1 indicates that a visa issued is recorded in the VIS, the competent asylum authority shall have access to consult the following data of the application file and linked application file(s) of the applicant pursuant to Article 8(3), and, as regards the data listed in point (e) of the spouse and children, pursuant to Article 8(4), for the sole purpose referred to in paragraph 1:

(a) the application number;

(b) the data taken from the application form, referred to in Article 9(4)(a), (b) and (c);

(c) photographs;

(d) the data entered in respect of any visa issued, annulled, revoked, or whose validity is extended or shortened, referred to in Articles 10, 13 and 14;

(e) the data referred to in Article 9(4)(a) and (b) of the linked application file(s) on the spouse and children.

3. The consultation of the VIS pursuant to paragraphs 1 and 2 of this Article shall be carried out only by the designated national authorities referred to in Article 21(6) of Regulation (EC) No 343/2003.

CHAPTER IV

RETENTION AND AMENDMENT OF THE DATA

Article 23

Retention period for data storage

1. Each application file shall be stored in the VIS for a maximum of five years, without prejudice to the deletion referred to in Articles 24 and 25 and to the keeping of records referred to in Article 34.

That period shall start:

(a) on the expiry date of the visa, if a visa has been issued;

(b) on the new expiry date of the visa, if a visa has been extended;

(c) on the date of the creation of the application file in the VIS, if the application has been withdrawn, closed or discontinued;

(d) on the date of the decision of the visa authority if a visa has been refused, annulled, shortened or revoked.

2. Upon expiry of the period referred to in paragraph 1, the VIS shall automatically delete the application file and the link(s) to this file as referred to in Article 8(3) and (4).

Article 24

Amendment of data

1. Only the Member State responsible shall have the right to amend data which it has transmitted to the VIS, by correcting or deleting such data.

2. If a Member State has evidence to suggest that data processed in the VIS are inaccurate or that data were processed in the VIS contrary to this Regulation, it shall inform the Member State responsible immediately. Such message may be transmitted by the infrastructure of the VIS.

3. The Member State responsible shall check the data concerned and, if necessary, correct or delete them immediately.

Article 25

Advance data deletion

1. Where, before expiry of the period referred to in Article 23(1), an applicant has acquired the nationality of a Member State, the application files and the links referred to in Article 8(3) and (4) relating to him or her shall be deleted without delay from the VIS by the Member State which created the respective application file(s) and links.

2. Each Member State shall inform the Member State(s) responsible without delay if an applicant has acquired its nationality. Such message may be transmitted by the infrastructure of the VIS.

3. If the refusal of a visa has been annulled by a court or an appeal body, the Member State which refused the visa shall delete the data referred to in Article 12 without delay as soon as the decision to annul the refusal of the visa becomes final.

CHAPTER V

OPERATION AND RESPONSIBILITIES

Article 26

Operational management

1. After a transitional period, a management authority (the Management Authority), funded from the general budget of the European Union, shall be responsible for the operational management of the central VIS and the national interfaces. The Management Authority shall ensure, in cooperation with the Member States, that at all times the best available technology, subject to a cost-benefit analysis, is used for the central VIS and the national interfaces.

2. The Management Authority shall also be responsible for the following tasks relating to the communication infrastructure between the central VIS and the national interfaces:

(a) supervision;

(b) security;

(c) the coordination of relations between the Member States and the provider.

3. The Commission shall be responsible for all other tasks relating to the Communication Infrastructure between the central VIS and the national interfaces, in particular:

(a) tasks relating to implementation of the budget;

(b) acquisition and renewal;

(c) contractual matters.

4. During a transitional period before the Management Authority takes up its responsibilities, the Commission shall be responsible for the operational management of the VIS. The Commission may delegate that task and tasks relating to implementation of the budget, in accordance with Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities [1], to national public-sector bodies in two different Member States.

5. Each national public-sector body referred to in paragraph 4 shall meet the following selection criteria:

(a) it must demonstrate that it has extensive experience in operating a large-scale information system;

(b) it must have considerable expertise in the service and security requirements of a large-scale information system;

(c) it must have sufficient and experienced staff with the appropriate professional expertise and linguistic skills to work in an international cooperation environment such as that required by the VIS;

[1] OJ L 248, 16.9.2002, p. 1. Regulation as last amended by Regulation (EC) No 1525/2007 (OJ L 343, 27.12.2007, p. 9).

(d) it must have a secure and custom-built facility infrastructure able, in particular, to back up and guarantee the continuous functioning of large-scale IT systems; and

(e) its administrative environment must allow it to implement its tasks properly and avoid any conflict of interests.

6. Prior to any delegation as referred to in paragraph 4 and at regular intervals thereafter, the Commission shall inform the European Parliament and the Council of the terms of the delegation, its precise scope, and the bodies to which tasks are delegated.

7. Where the Commission delegates its responsibility during the transitional period pursuant to paragraph 4, it shall ensure that the delegation fully respects the limits set by the institutional system laid out in the Treaty. It shall ensure, in particular, that the delegation does not adversely affect any effective control mechanism under Community law, whether by the Court of Justice, the Court of Auditors or the European Data Protection Supervisor.

8. Operational management of the VIS shall consist of all the tasks necessary to keep the VIS functioning 24 hours a day, seven days a week in accordance with this Regulation, in particular the maintenance work and technical developments necessary to ensure that the system functions at a satisfactory level of operational quality, in particular as regards the time required for interrogation of the central database by consular posts, which should be as short as possible.

9. Without prejudice to Article 17 of the Staff Regulations of officials of the European Communities, laid down in Regulation (EEC, Euratom, ECSC) No 259/68 ([1]), the Management Authority shall apply appropriate rules of professional secrecy or other equivalent duties of confidentiality to all its staff required to work with VIS data. This obligation shall also apply after such staff leave office or employment or after the termination of their activities.

Article 27

Location of the central Visa Information System

The principal central VIS, which performs technical supervision and administration functions, shall be located in Strasbourg (France) and a back-up central VIS, capable of ensuring all functionalities of the principal central VIS in the event of failure of the system, shall be located in Sankt Johann im Pongau (Austria).

([1]) OJ L 56, 4.3.1968, p. 1. Regulation as last amended by Regulation (EC, Euratom) No 337/2007 (OJ L 90, 30.3.2007, p. 1).

Article 28

Relation to the national systems

1. The VIS shall be connected to the national system of each Member State via the national interface in the Member State concerned.

2. Each Member State shall designate a national authority, which shall provide the access of the competent authorities referred to in Article 6(1) and (2) to the VIS, and connect that national authority to the national interface.

3. Each Member State shall observe automated procedures for processing the data.

4. Each Member State shall be responsible for:

(a) the development of the national system and/or its adaptation to the VIS according to Article 2(2) of Decision 2004/512/EC;

(b) the organisation, management, operation and maintenance of its national system;

(c) the management and arrangements for access of the duly authorised staff of the competent national authorities to the VIS in accordance with this Regulation and to establish and regularly update a list of such staff and their profiles;

(d) bearing the costs incurred by the national system and the costs of their connection to the national interface, including the investment and operational costs of the communication infrastructure between the national interface and the national system.

5. Before being authorised to process data stored in the VIS, the staff of the authorities having a right to access the VIS shall receive appropriate training about data security and data protection rules and shall be informed of any relevant criminal offences and penalties.

Article 29

Responsibility for the use of data

1. Each Member State shall ensure that the data are processed lawfully, and in particular that only duly authorised staff have access to data processed in the VIS for the performance of their tasks in accordance with this Regulation. The Member State responsible shall ensure in particular that:

(a) the data are collected lawfully;

(b) the data are transmitted lawfully to the VIS;

(c) the data are accurate and up-to-date when they are transmitted to the VIS.

2. The management authority shall ensure that the VIS is operated in accordance with this Regulation and its implementing rules referred to in Article 45(2). In particular, the management authority shall:

(a) take the necessary measures to ensure the security of the central VIS and the communication infrastructure between the central VIS and the national interfaces, without prejudice to the responsibilities of each Member State;

(b) ensure that only duly authorised staff have access to data processed in the VIS for the performance of the tasks of the management authority in accordance with this Regulation.

3. The management authority shall inform the European Parliament, the Council and the Commission of the measures which it takes pursuant to paragraph 2.

Article 30

Keeping of VIS data in national files

1. Data retrieved from the VIS may be kept in national files only when necessary in an individual case, in accordance with the purpose of the VIS and in accordance with the relevant legal provisions, including those concerning data protection, and for no longer than necessary in that individual case.

2. Paragraph 1 shall be without prejudice to the right of a Member State to keep in its national files data which that Member State entered in the VIS.

3. Any use of data which does not comply with paragraphs 1 and 2 shall be considered a misuse under the national law of each Member State.

Article 31

Communication of data to third countries or international organisations

1. Data processed in the VIS pursuant to this Regulation shall not be transferred or made available to a third country or to an international organisation.

2. By way of derogation from paragraph 1, the data referred to in Article 9(4)(a), (b), (c), (k) and (m) may be transferred or made available to a third country or to an international organisation listed in the Annex if necessary in individual cases for the purpose of proving the identity of third-country nationals, including for the purpose of return, only where the following conditions are satisfied:

(a) the Commission has adopted a decision on the adequate protection of personal data in that third country in accordance with Article 25(6) of Directive 95/46/EC, or a readmission agreement is in force between the Community and that third country, or the provisions of Article 26(1)(d) of Directive 95/46/EC apply;

(b) the third country or international organisation agrees to use the data only for the purpose for which they were provided;

(c) the data are transferred or made available in accordance with the relevant provisions of Community law, in particular readmission agreements, and the national law of the Member State which transferred or made the data available, including the legal provisions relevant to data security and data protection; and

(d) the Member State(s) which entered the data in the VIS has given its consent.

3. Such transfers of personal data to third countries or international organisations shall not prejudice the rights of refugees and persons requesting international protection, in particular as regards non-refoulement.

Article 32

Data security

1. The Member State responsible shall ensure the security of the data before and during transmission to the national interface. Each Member State shall ensure the security of the data which it receives from the VIS.

2. Each Member State shall, in relation to its national system, adopt the necessary measures, including a security plan, in order to:

(a) physically protect data, including by making contingency plans for the protection of critical infrastructure;

(b) deny unauthorised persons access to national installations in which the Member State carries out operations in accordance with the purposes of the VIS (checks at entrance to the installation);

(c) prevent the unauthorised reading, copying, modification or removal of data media (data media control);

(d) prevent the unauthorised input of data and the unauthorised inspection, modification or deletion of stored personal data (storage control);

(e) prevent the unauthorised processing of data in the VIS and any unauthorised modification or deletion of data processed in the VIS (control of data entry);

(f) ensure that persons authorised to access the VIS have access only to the data covered by their access authorisation, by means of individual and unique user identities and confidential access modes only (data access control);

(g) ensure that all authorities with a right of access to the VIS create profiles describing the functions and responsibilities of persons who are authorised to access, enter, update, delete and search the data and make these profiles available to the National Supervisory Authorities referred to in Article 41 without delay at their request (personnel profiles);

(h) ensure that it is possible to verify and establish to which bodies personal data may be transmitted using data communication equipment (communication control);

(i) ensure that it is possible to verify and establish what data have been processed in the VIS, when, by whom and for what purpose (control of data recording);

(j) prevent the unauthorised reading, copying, modification or deletion of personal data during the transmission of personal data to or from the VIS or during the transport of data media, in particular by means of appropriate encryption techniques (transport control);

(k) monitor the effectiveness of the security measures referred to in this paragraph and take the necessary organisational measures related to internal monitoring to ensure compliance with this Regulation (self-auditing).

3. The Management Authority shall take the necessary measures in order to achieve the objectives set out in paragraph 2 as regards the operation of the VIS, including the adoption of a security plan.

Article 33

Liability

1. Any person who, or Member State which, has suffered damage as a result of an unlawful processing operation or any act incompatible with this Regulation shall be entitled to receive compensation from the Member State which is responsible for the damage suffered. That Member State shall be exempted from its liability, in whole or in part, if it proves that it is not responsible for the event giving rise to the damage.

2. If any failure of a Member State to comply with its obligations under this Regulation causes damage to the VIS, that Member State shall be held liable for such damage, unless and insofar as the Management Authority or another Member State failed to take reasonable measures to prevent the damage from occurring or to minimise its impact.

3. Claims for compensation against a Member State for the damage referred to in paragraphs 1 and 2 shall be governed by the provisions of national law of the defendant Member State.

Article 34

Keeping of records

1. Each Member State and the Management Authority shall keep records of all data processing operations within the VIS. These records shall show the purpose of access referred to in Article 6(1) and in Articles 15 to 22, the date and time, the type of data transmitted as referred to in Articles 9 to 14, the type of data used for interrogation as referred to in Articles 15(2), 17, 18(1) to (3), 19(1), 20(1), 21(1) and 22(1) and the name of the authority entering or retrieving the data. In addition, each Member State shall keep records of the staff duly authorised to enter or retrieve the data.

2. Such records may be used only for the data-protection monitoring of the admissibility of data processing as well as to ensure data security. The records shall be protected by appropriate measures against unauthorised access and deleted after a period of one year after the retention period referred to in Article 23(1) has expired, if they are not required for monitoring procedures which have already begun.

Article 35

Self-monitoring

Member States shall ensure that each authority entitled to access VIS data takes the measures necessary to comply with this Regulation and cooperates, where necessary, with the National Supervisory Authority.

Article 36

Penalties

Member States shall take the necessary measures to ensure that any misuse of data entered in the VIS is punishable by penalties, including administrative and/or criminal penalties in accordance with national law, that are effective, proportionate and dissuasive.

CHAPTER VI

RIGHTS AND SUPERVISION ON DATA PROTECTION

Article 37

Right of information

1. Applicants and the persons referred to in Article 9(4)(f) shall be informed of the following by the Member State responsible:

(a) the identity of the controller referred to in Article 41(4), including his contact details;

(b) the purposes for which the data will be processed within the VIS;

(c) the categories of recipients of the data, including the authorities referred to in Article 3;

(d) the data retention period;

(e) that the collection of the data is mandatory for the examination of the application;

(f) the existence of the right of access to data relating to them, and the right to request that inaccurate data relating to them be corrected or that unlawfully processed data relating to them be deleted, including the right to receive information on the procedures for exercising those rights and the contact details of the National Supervisory Authorities referred to in Article 41(1), which shall hear claims concerning the protection of personal data.

2. The information referred to in paragraph 1 shall be provided in writing to the applicant when the data from the application form, the photograph and the fingerprint data as referred to in Article 9(4), (5) and (6) are collected.

3. The information referred to in paragraph 1 shall be provided to the persons referred to in Article 9(4)(f) on the forms to be signed by those persons providing proof of invitation, sponsorship and accommodation. In the absence of such a form signed by those persons, this information shall be provided in accordance with Article 11 of Directive 95/46/EC.

Article 38

Right of access, correction and deletion

1. Without prejudice to the obligation to provide other information in accordance with Article 12(a) of Directive 95/46/EC, any person shall have the right to obtain communication of the data relating to him recorded in the VIS and of the Member State which transmitted them to the VIS. Such access to data may be granted only by a Member State. Each Member State shall record any requests for such access.

2. Any person may request that data relating to him which are inaccurate be corrected and that data recorded unlawfully be deleted. The correction and deletion shall be carried out without delay by the Member State responsible, in accordance with its laws, regulations and procedures.

3. If the request as provided for in paragraph 2 is made to a Member State other than the Member State responsible, the authorities of the Member State with which the request was lodged shall contact the authorities of the Member State responsible within a period of 14 days. The Member State responsible shall check the accuracy of the data and the lawfulness of their processing in the VIS within a period of one month.

4. If it emerges that data recorded in the VIS are inaccurate or have been recorded unlawfully, the Member State responsible shall correct or delete the data in accordance with Article 24(3). The Member State responsible shall confirm in writing to the person concerned without delay that it has taken action to correct or delete data relating to him.

5. If the Member State responsible does not agree that data recorded in the VIS are inaccurate or have been recorded unlawfully, it shall explain in writing to the person concerned without delay why it is not prepared to correct or delete data relating to him.

6. The Member State responsible shall also provide the person concerned with information explaining the steps which he can take if he does not accept the explanation provided. This shall include information on how to bring an action or a complaint before the competent authorities or courts of that Member State and on any assistance, including from the national supervisory authorities referred to in Article 41(1), that is available in accordance with the laws, regulations and procedures of that Member State.

Article 39

Cooperation to ensure the rights on data protection

1. The Member States shall cooperate actively to enforce the rights laid down in Article 38(2), (3) and (4).

2. In each Member State, the national supervisory authority shall, upon request, assist and advise the person concerned in exercising his right to correct or delete data relating to him in accordance with Article 28(4) of Directive 95/46/EC.

3. The National Supervisory Authority of the Member State responsible which transmitted the data and the National Supervisory Authorities of the Member States with which the request was lodged shall cooperate to this end.

Article 40

Remedies

1. In each Member State any person shall have the right to bring an action or a complaint before the competent authorities or courts of that Member State which refused the right of access to or the right of correction or deletion of data relating to him, provided for in Article 38(1) and (2).

2. The assistance of the National Supervisory Authorities referred to in Article 39(2) shall remain available throughout the proceedings.

Article 41

Supervision by the National Supervisory Authority

1. The authority or authorities designated in each Member State and endowed with the powers referred to in Article 28 of Directive 95/46/EC (the National Supervisory Authority) shall monitor independently the lawfulness of the processing of personal data referred to in Article 5(1) by the Member State in question, including their transmission to and from the VIS.

2. The National Supervisory Authority shall ensure that an audit of the data processing operations in the national system is carried out in accordance with relevant international auditing standards at least every four years.

3. Member States shall ensure that their National Supervisory Authority has sufficient resources to fulfil the tasks entrusted to it under this Regulation.

4. In relation to the processing of personal data in the VIS, each Member State shall designate the authority which is to be considered as controller in accordance with Article 2(d) of Directive 95/46/EC and which shall have central responsibility for the processing of data by that Member State. Each Member State shall communicate the details of that authority to the Commission.

5. Each Member State shall supply any information requested by the National Supervisory Authorities and shall, in particular, provide them with information on the activities carried out in accordance with Articles 28 and 29(1), grant them access to the lists referred to in Article 28(4)(c) and to its records as referred to in Article 34 and allow them access at all times to all their premises.

Article 42

Supervision by the European Data Protection Supervisor

1. The European Data Protection Supervisor shall check that the personal data processing activities of the Management Authority are carried out in accordance with this Regulation. The duties and powers referred to in Articles 46 and 47 of Regulation (EC) No 45/2001 shall apply accordingly.

2. The European Data Protection Supervisor shall ensure that an audit of the Management Authority's personal data processing activities is carried out in accordance with relevant international auditing standards at least every four years. A report of such audit shall be sent to the European Parliament, the Council, the Management Authority, the Commission and the National Supervisory Authorities. The Management Authority shall be given an opportunity to make comments before the report is adopted.

3. The Management Authority shall supply information requested by the European Data Protection Supervisor, give him access to all documents and to its records referred to in Article 34(1) and allow him access to all its premises, at any time.

Article 43

Cooperation between National Supervisory Authorities and the European Data Protection Supervisor

1. The National Supervisory Authorities and the European Data Protection Supervisor, each acting within the scope of their respective competences, shall cooperate actively within the framework of their responsibilities and shall ensure coordinated supervision of the VIS and the national systems.

2. They shall, each acting within the scope of their respective competences, exchange relevant information, assist each other in carrying out audits and inspections, examine difficulties of interpretation or application of this Regulation, study problems

with the exercise of independent supervision or with the exercise of the rights of data subjects, draw up harmonised proposals for joint solutions to any problems and promote awareness of data protection rights, as necessary.

3. The National Supervisory Authorities and the European Data Protection Supervisor shall meet for that purpose at least twice a year. The costs and servicing of these meetings shall be b for the account of the European Data Protection Supervisor. Rules of procedure shall be adopted at the first meeting. Further working methods shall be developed jointly as necessary.

4. A joint report of activities shall be sent to the European Parliament, the Council, the Commission and the Management Authority every two years. This report shall include a chapter of each Member State prepared by the National Supervisory Authority of that Member State.

Article 44

Data protection during the transitional period

Where the Commission delegates its responsibilities during the transitional period to another body or bodies, pursuant to Article 26(4) of this Regulation, it shall ensure that the European Data Protection Supervisor has the right and is able to exercise his tasks fully, including the carrying out of on-the-spot checks, and to exercise any other powers conferred on him by Article 47 of Regulation (EC) No 45/2001.

CHAPTER VII

FINAL PROVISIONS

Article 45

Implementation by the Commission

1. The central VIS, the national interface in each Member State and the communication infrastructure between the central VIS and the national interfaces shall be implemented by the Commission as soon as possible after the entry into force of this Regulation, including the functionalities for processing the biometric data referred to in Article 5(1)(c).

2. The measures necessary for the technical implementation of the central VIS, the national interfaces and the communication infrastructure between the central VIS and the national interfaces shall be adopted in accordance with the procedure referred to in Article 49(2), in particular:

(a) for entering the data and linking applications in accordance with Article 8;

(b) for accessing the data in accordance with Article 15 and Articles 17 to 22;

(c) for amending, deleting and advance deleting of data in accordance with Articles 23 to 25;

(d) for keeping and accessing the records in accordance with Article 34;

(e) for the consultation mechanism and the procedures referred to in Article 16.

Article 46

Integration of the technical functionalities of the Schengen Consultation Network

The consultation mechanism referred to in Article 16 shall replace the Schengen Consultation Network from the date determined in accordance with the procedure referred to in Article 49(3) when all those Member States which use the Schengen Consultation Network at the date of entry into force of this Regulation have notified the legal and technical arrangements for the use of the VIS for the purpose of consultation between central visa authorities on visa applications according to Article 17(2) of the Schengen Convention.

Article 47

Start of transmission

Each Member State shall notify the Commission that it has made the necessary technical and legal arrangements to transmit the data referred to in Article 5(1) to the central VIS via the national interface.

Article 48

Start of operations

1. The Commission shall determine the date from which the VIS is to start operations, when:

(a) the measures referred to in Article 45(2) have been adopted;

(b) the Commission has declared the successful completion of a comprehensive test of the VIS, which shall be conducted by the Commission together with Member States;

(c) following validation of technical arrangements, the Member States have notified the Commission that they have made the necessary technical and legal arrangements to collect and transmit the data referred to in Article 5(1) to the VIS for all applications in the first region determined according to paragraph 4, including arrangements for the collection and/or transmission of the data on behalf of another Member State.

2. The Commission shall inform the European Parliament of the results of the test carried out in accordance with paragraph 1(b).

3. In every other region, the Commission shall determine the date from which the transmission of the data in Article 5(1) becomes mandatory when Member States have notified the Commission that they have made the necessary technical and legal arrangements to collect and transmit the data referred to in Article 5(1) to the VIS for all applications in the region concerned, including arrangements for the collection and/or transmission of the data on behalf of another Member State. Before that date, each Member State may start operations in any of these regions, as soon as it has notified to the Commission that it has made the necessary technical and legal arrangements to collect and transmit at least the data referred to in Article 5(1)(a) and (b) to the VIS.

4. The regions referred to in paragraphs 1 and 3 shall be determined in accordance with the procedure referred to in Article 49(3). The criteria for the determination of these regions shall be the risk of illegal immigration, threats to the internal security of the Member States and the feasibility of collecting biometrics from all locations in this region.

5. The Commission shall publish the dates for the start of operations in each region in the *Official Journal of the European Union*.

6. No Member State shall consult the data transmitted by other Member States to the VIS before it or another Member State representing this Member State starts entering data in accordance with paragraphs 1 and 3.

Article 49

Committee

1. The Commission shall be assisted by the committee set up by Article 51(1) of Regulation (EC) No 1987/2006 of the European Parliament and of the Council of 20 December 2006 on the establishment, operation and use of the second generation Schengen Information System (SIS II) [1].

2. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be two months.

3. Where reference is made to this paragraph, Article 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be two months.

Article 50

Monitoring and evaluation

1. The Management Authority shall ensure that procedures are in place to monitor the functioning of the VIS against objectives relating to output, cost-effectiveness, security and quality of service.

2. For the purposes of technical maintenance, the Management Authority shall have access to the necessary information relating to the processing operations performed in the VIS.

3. Two years after the VIS is brought into operation and every two years thereafter, the Management Authority shall submit to the European Parliament, the Council and the Commission a report on the technical functioning of the VIS, including the security thereof.

4. Three years after the VIS is brought into operation and every four years thereafter, the Commission shall produce an overall evaluation of the VIS. This overall evaluation shall include an examination of results achieved against objectives and an assessment of the continuing validity of the underlying rationale, the application of this Regulation in respect of the VIS, the security of the VIS, the use made of the provisions referred to in Article 31 and any implications for future operations. The Commission shall transmit the evaluation to the European Parliament and the Council.

5. Before the end of the periods referred to in Article 18(2) the Commission shall report on the technical progress made regarding the use of fingerprints at external borders and its implications for the duration of searches using the number of the visa sticker in combination with verification of the fingerprints of the visa holder, including whether the expected duration of such a search entails excessive waiting time at border crossing points. The Commission shall transmit the evaluation to the European Parliament and the Council. On the basis of that evaluation, the European Parliament or the Council may invite the Commission to propose, if necessary, appropriate amendments to this Regulation.

6. Member States shall provide the Management Authority and the Commission with the information necessary to draft the reports referred to in paragraph 3, 4 and 5.

7. The Management Authority shall provide the Commission with the information necessary to produce the overall evaluations referred to in paragraph 4.

[1] OJ L 381, 28.12.2006, p. 4.

8. During the transitional period before the Management Authority takes up its responsibilities, the Commission shall be responsible for producing and submitting the reports referred to in paragraph 3.

Article 51

Entry into force and application

1. This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

2. It shall apply from the date referred to in Article 48(1).

3. Articles 26, 27, 32, 45, 48(1), (2) and (4) and Article 49 shall apply as from 2 September 2008.

4. During the transitional period referred to in Article 26(4), references in this Regulation to the Management Authority shall be construed as references to the Commission.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaty establishing the European Community.

Done at Strasbourg, 9 July 2008.

For the European Parliament	*For the Council*
The President	*The President*
H.-G. PÖTTERING	J.-P. JOUYET

ANNEX

List of international organisations referred to in Article 31(2)

1. UN organisations (such as UNHCR);
2. International Organization for Migration (IOM);
3. The International Committee of the Red Cross.

DECISIONS ADOPTED JOINTLY BY THE EUROPEAN PARLIAMENT AND THE COUNCIL

DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 July 2008

on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ([2]),

Whereas:

(1) On 7 May 2003 the Commission issued a Communication to the Council and the European Parliament entitled 'Enhancing the Implementation of the New Approach Directives'. In its Resolution of 10 November 2003 ([3]), the Council acknowledged the importance of the New Approach as an appropriate and efficient regulatory model allowing technological innovation and enhancing the competitiveness of European industry, and confirmed the necessity of extending the application of its principles to new areas, while recognising the need for a clearer framework for conformity assessment, accreditation and market surveillance.

(2) This Decision lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. This Decision therefore constitutes a general framework of a horizontal nature for future legislation harmonising the conditions for the marketing of products and a reference text for existing legislation.

(3) This Decision provides, in the form of reference provisions, definitions and general obligations for economic operators and a range of conformity assessment procedures from which the legislator can select as appropriate. It also lays down rules for CE marking. Furthermore, reference provisions are provided as regards the requirements for conformity assessment bodies to be notified to the Commission as competent to carry out the relevant conformity assessment procedures and as regards the notification procedures. In addition, this Decision includes reference provisions concerning procedures for dealing with products presenting a risk in order to ensure the safety of the market place.

(4) Whenever legislation is drawn up which concerns a product already subject to other Community acts, those acts must be taken into account to ensure the consistency of all legislation concerning the same product.

(5) However, the specificities of sectoral needs may provide grounds for recourse to other regulatory solutions. In particular, that is the case where there are specific, comprehensive legal systems already in place in a sector, as for example in the fields of feed and food, cosmetic and tobacco products, common market organisations for agricultural products, plant health and plant protection, human blood and tissues, medicinal products for human and veterinary use and chemicals, or where sectoral needs require specific adaptation of the common principles and reference provisions, as for example in the fields of medical devices, construction products and marine equipment. Such adaptations may also be related to the modules set out in Annex II.

([1]) OJ C 120, 16.5.2008, p. 1.

([2]) Opinion of the European Parliament of 21 February 2008 (not yet published in the Official Journal) and Council Decision of 23 June 2008.

([3]) OJ C 282, 25.11.2003, p. 3.

(6) Whenever legislation is drawn up, the legislator may depart, totally or partially, from the common principles and reference provisions laid down in this Decision on account of the specificities of the sector concerned. Any such departure should be justified.

(7) Although the incorporation of the provisions of this Decision in future legislative acts cannot be required by law, the co-legislators adopting this Decision have entered into a clear political commitment which they should respect in any legislative act falling within the scope of this Decision.

(8) Specific product legislation should, wherever possible, avoid going into technical detail but should limit itself to the expression of essential requirements. Such legislation should, where appropriate, have recourse to harmonised standards adopted in accordance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services ([1]) for the purpose of expressing detailed technical specifications. This Decision builds on and complements the standardisation system provided for by that Directive. However, where health and safety, the protection of consumers or of the environment, other aspects of public interest, or clarity and practicability so require, detailed technical specifications may be set out in the legislation concerned.

(9) The presumption of conformity to a legal provision conferred by conformity to a harmonised standard should enhance recourse to compliance with harmonised standards.

(10) It should be possible for Member States or the Commission to object in cases in which a harmonised standard does not entirely satisfy the requirements of Community harmonisation legislation. The Commission should be able to decide not to publish such a standard. To that end, the Commission should, in such manner as appropriate, consult sectoral representatives and Member States before the Committee set up by Article 5 of Directive 98/34/EC delivers its opinion.

(11) The essential requirements should be worded precisely enough to create legally binding obligations. They should be formulated so as to make it possible to assess conformity with them even in the absence of harmonised standards or where the manufacturer chooses not to apply a harmonised standard. The degree of detail of the wording will depend on the characteristics of each sector.

(12) The successful accomplishment of the required conformity assessment procedure enables economic operators to demonstrate and the competent authorities to ensure that products made available on the market conform to the requirements applicable.

(13) The modules for the conformity assessment procedures to be used in the Community harmonisation legislation were initially set out in Council Decision 93/465/EEC of 22 July 1993 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 ([2]). This Decision replaces that Decision.

(14) It is necessary to offer a choice of clear, transparent and coherent conformity assessment procedures, restricting the possible variants. This Decision provides for a menu of modules, enabling the legislator to choose a procedure from the least to the most stringent, in proportion to the level of risk involved and the level of safety required.

(15) For the purposes of ensuring inter-sectoral coherence and avoiding ad-hoc variants, it is desirable that the procedures which are to be used in sectoral legislation be chosen from among the modules, in accordance with the general criteria set out.

(16) In the past, legislation on the free movement of goods has used a set of terms partly without defining them and guidelines for explanation and interpretation have consequently been necessary. Where legal definitions have been introduced they differ to some extent in their wording and sometimes in their meaning, which gives rise to difficulties in their interpretation and correct implementation. This Decision therefore introduces clear definitions of certain fundamental concepts.

(17) Products that are placed on the Community market should comply with the relevant applicable Community legislation, and economic operators should be responsible for the compliance of products, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety, and the protection of consumers and of the environment, and to guarantee fair competition on the Community market.

(18) All economic operators are expected to act responsibly and in full accordance with the legal requirements applicable when placing or making products available on the market.

(19) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only products which are in conformity with the applicable legislation. This Decision provides a clear and proportionate distribution of obligations which correspond to the role of each operator in the supply and distribution process.

([1]) OJ L 204, 21.7.1998, p. 37. Directive as last amended by Council Directive 2006/96/EC (OJ L 363, 20.12.2006, p. 81).

([2]) OJ L 220, 30.8.1993, p. 23.

(20) As certain tasks can be executed only by the manufacturer, it is necessary to distinguish clearly between the manufacturer and operators further down the distribution chain. It is also necessary to distinguish clearly between the importer and the distributor, as the importer introduces products from third countries to the Community market. The importer has thus to make sure that those products comply with the applicable Community requirements.

(21) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure. Conformity assessment should therefore remain the obligation of the manufacturer alone.

(22) It is necessary to ensure that products from third countries entering the Community market comply with all applicable Community requirements, and in particular that appropriate assessment procedures have been carried out by manufacturers with regard to those products. Provision should therefore be made for importers to make sure that the products they place on the market comply with the applicable requirements and that they do not place on the market products which do not comply with such requirements or present a risk. For the same reason, provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that product marking and documentation drawn up by manufacturers are available for inspection by the supervisory authorities.

(23) The distributor makes a product available on the market after it has been placed on the market by the manufacturer or the importer and must act with due care to ensure that its handling of the product does not adversely affect the compliance of the product. Both importers and distributors are expected to act with due care in relation to the requirements applicable when placing or making products available on the market.

(24) Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products ([1]) applies, *inter alia*, to products not in conformity with Community harmonisation legislation. Manufacturers and importers who have placed non-compliant products on the Community market are liable for damages under that Directive.

(25) When placing a product on the market, every importer should indicate on the product his name and the address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the product does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the product.

(26) Any economic operator that either places a product on the market under his own name or trademark or modifies a product in such a way that compliance with applicable requirements may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.

(27) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by national authorities, and should be prepared to participate actively, providing the competent authorities with all necessary information relating to the product concerned.

(28) Ensuring traceability of a product throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant products available on the market.

(29) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008 of the European Parliament and the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products ([2]). Rules governing the affixing of the CE marking, to be applied in Community harmonisation legislation providing for the use of that marking, should be laid down in this Decision.

(30) The CE marking should be the only marking of conformity indicating that a product is in conformity with Community harmonisation legislation. However, other markings may be used as long as they contribute to the improvement of consumer protection and are not covered by Community harmonisation legislation.

(31) It is crucial to make clear to both manufacturers and users that by affixing the CE marking to a product the manufacturer declares that the product is in conformity with all applicable requirements and that he takes full responsibility therefor.

(32) In order better to evaluate the effectiveness of the CE marking and to define strategies aimed at preventing abuse, the Commission should monitor its implementation and report thereon to the European Parliament.

([1]) OJ L 210, 7.8.1985, p. 29. Directive as amended by Directive 1999/34/EC of the European Parliament and of the Council (OJ L 141, 4.6.1999, p. 20).

([2]) See page 30 of this Official Journal.

(33) The CE marking can be of value only if its affixing respects the conditions laid down in Community law. Member States should, therefore, ensure proper enforcement of those conditions and pursue violations and abuse of the CE marking by legal or other appropriate means.

(34) Member States are responsible for ensuring strong and efficient market surveillance on their territories and should allocate sufficient powers and resources to their market surveillance authorities.

(35) For the purpose of raising awareness regarding the CE marking, the Commission should launch an information campaign targeted primarily at economic operators, consumer and sectoral organisations and sales personnel, which are the most appropriate channels for conveying information to consumers.

(36) In certain circumstances the conformity assessment procedures prescribed by the applicable legislation require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.

(37) Experience has shown that the criteria set out in sectoral legislation which conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Community. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.

(38) In order to ensure a consistent level of quality in the performance of conformity assessment it is necessary not only to consolidate the requirements that conformity assessment bodies wishing to be notified must fulfil, but also, in parallel, to set requirements that notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies must fulfil.

(39) The system set out in this Decision is complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, its use should also be encouraged for the purposes of notification.

(40) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in the relevant sectoral legislation.

(41) Where Community harmonisation legislation provides for the selection of conformity assessment bodies for its implementation, transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Community the preferred means of demonstrating the technical competence of those bodies. However, national authorities may consider that they possess the appropriate means of carrying out this evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

(42) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the products to be placed on the Community market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.

(43) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.

(44) Since notified bodies may offer their services throughout the Community, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.

(45) In the interests of competitiveness, it is crucial that notified bodies apply the modules without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the modules must be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.

(46) To ensure the proper functioning of the certification process, certain procedures, such as exchanges of experience and information between notified bodies and notifying authorities and between notified bodies, should be consolidated.

(47) Community harmonisation legislation already provides for a safeguard procedure which applies only in the event of disagreement between Member States over measures taken by a Member State. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard clause procedure, with a view to making it more efficient and drawing on the expertise available in Member States.

(48) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to products presenting a risk to the health and safety of persons or to other aspects of public interest protection. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such products.

(49) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.

(50) Community legislation should take account of the specific situation of small and medium-sized enterprises as regards administrative burdens. However, rather than providing for general exceptions and derogations for such enterprises, which might imply that they or their products are second-rate or sub-quality and which might result in a complex legal situation for the national market surveillance authorities to supervise, Community legislation should provide for the situation of such enterprises to be taken into account in setting the rules for the selection and implementation of the most appropriate conformity assessment procedures and concerning the obligations placed on conformity assessment bodies to operate in a proportionate manner in relation to the size of undertakings and to the small serial or non-serial nature of the production concerned. This Decision provides the legislator with the flexibility necessary to take account of such a situation, without creating unnecessary specific and inappropriate solutions for small and medium-sized enterprises, and without compromising the protection of public interests.

(51) This Decision establishes provisions for conformity assessment bodies to perform their functions, while taking into consideration the specific situation of small and medium-sized enterprises and respecting the degree of rigour and level of protection required for products to comply with the legislative instruments applicable to them.

(52) Within one year of the publication of this Decision in the *Official Journal of the European Union*, the Commission should present an in-depth analysis in the field of consumer safety markings, followed by legislative proposals if necessary,

HAVE DECIDED AS FOLLOWS:

Article 1

General principles

1. Products placed on the Community market shall comply with all applicable legislation.

2. When placing products on the Community market, economic operators shall, in relation to their respective roles in the supply chain, be responsible for the compliance of their products with all applicable legislation.

3. Economic operators shall be responsible for ensuring that all information they provide with regard to their products is accurate, complete and in compliance with Community rules applicable.

Article 2

Subject matter and scope

This Decision sets out the common framework of general principles and reference provisions for the drawing up of Community legislation harmonising the conditions for the marketing of products (Community harmonisation legislation).

Community harmonisation legislation shall have recourse to the general principles set out in this Decision and to the relevant reference provisions of Annexes I, II and III. However, Community legislation may depart from those general principles and reference provisions if that is appropriate on account of the specificities of the sector concerned, especially if comprehensive legal systems are already in place.

Article 3

Level of protection of public interests

1. As regards the protection of public interests, Community harmonisation legislation shall restrict itself to setting out the essential requirements determining the level of such protection and shall express those requirements in terms of the results to be achieved.

Where recourse to essential requirements is not possible or not appropriate, in view of the objective of ensuring the adequate protection of consumers, public health and the environment or other aspects of public interest protection, detailed specifications may be set out in the Community harmonisation legislation concerned.

2. Where Community harmonisation legislation sets out essential requirements, it shall provide for recourse to be had to harmonised standards, adopted in accordance with Directive 98/34/EC, which shall express those requirements in technical terms and which shall, alone or in conjunction with other harmonised standards, provide for the presumption of conformity with those requirements, while maintaining the possibility of setting the level of protection by other means.

Article 4

Conformity assessment procedures

1. Where Community harmonisation legislation requires conformity assessment to be performed in respect of a particular product, the procedures which are to be used shall be chosen from among the modules set out and specified in Annex II, in accordance with the following criteria:

(a) whether the module concerned is appropriate to the type of product;

(b) the nature of the risks entailed by the product and the extent to which conformity assessment corresponds to the type and degree of risk;

(c) where third party involvement is mandatory, the need for the manufacturer to have a choice between quality assurance and product certification modules set out in Annex II;

(d) the need to avoid imposing modules which would be too burdensome in relation to the risks covered by the legislation concerned.

2. Where a product is subject to several Community acts within the scope of this Decision, consistency among conformity assessment procedures shall be ensured by the legislator.

3. The modules referred to in paragraph 1 shall be applied as appropriate to the product concerned and in accordance with the instructions set out in those modules.

4. For custom-made products and small series production, the technical and administrative conditions relating to conformity assessment procedures shall be alleviated.

5. When applying the modules referred to in paragraph 1, and wherever applicable and relevant, the legislative instrument may:

(a) regarding technical documentation, require information additional to that which is already stipulated in the modules;

(b) regarding the time for which the manufacturer and/or notified body are obliged to keep any kind of documentation, alter the period stipulated in the modules;

(c) specify the manufacturer's choice as to whether the tests are carried out either by an accredited in-house body or under the responsibility of a notified body chosen by the manufacturer;

(d) where product verification is performed, specify the manufacturer's choice as to whether the examinations and tests to check the conformity of the products with the appropriate requirements will be carried out, by examination and testing of every product, or by examination and testing of the products on a statistical basis;

(e) provide for the EC-type examination certificate to have a period of validity;

(f) regarding the EC-type examination certificate, specify relevant information relating to conformity assessment and in-service control to be included in it or its annexes;

(g) provide for different arrangements regarding the obligations of the notified body to inform its notifying authorities;

(h) if the notified body carries out periodic audits, specify their frequency.

6. When applying the modules referred to in paragraph 1, and wherever applicable and relevant, the legislative instrument shall:

(a) where product checks and/or verification are performed, determine the products concerned, the appropriate tests, the adequate sampling schemes, the operational characteristics of the statistical method to be applied and the corresponding action to be taken by the notified body and/or the manufacturer;

(b) where EC-type examination is performed, determine the appropriate manner (design type, production type, design and production type) and the specimens required.

7. An appeal procedure against decisions of the notified body shall be available.

Article 5

EC declaration of conformity

Where Community harmonisation legislation requires a statement by the manufacturer that fulfilment of the requirements relating to a product has been demonstrated (EC declaration of conformity), the legislation shall provide that a single declaration shall be drawn up in respect of all Community acts applicable to the product containing all information required for the identification of Community harmonisation legislation to which the declaration relates, and giving the publication references of the acts concerned.

Article 6

Conformity assessment

1. Where Community harmonisation legislation requires conformity assessment, it may provide for that assessment to be carried out by public authorities, manufacturers or notified bodies.

2. Where Community harmonisation legislation provides for conformity assessment to be carried out by public authorities, the legislation shall provide that the conformity assessment bodies on which those authorities rely for technical assessments must comply with the same criteria as those set out in this Decision for notified bodies.

Article 7

Reference provisions

The reference provisions for Community harmonisation legislation for products shall be as set out in Annex I.

Article 8

Repeal

Decision 93/465/EEC is hereby repealed.

References to the repealed Decision shall be construed as references to this Decision.

Done at Strasbourg, 9 July 2008.

For the European Parliament	*For the Council*
The President	*The President*
H.-G. PÖTTERING	J.P. JOUYET

ANNEX I

REFERENCE PROVISIONS FOR COMMUNITY HARMONISATION LEGISLATION FOR PRODUCTS

Chapter R1

Definitions

Article R1

Definitions

For the purposes of this ... [act] the following definitions shall apply:

1. 'making available on the market' shall mean any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;

2. 'placing on the market' shall mean the first making available of a product on the Community market;

3. 'manufacturer' shall mean any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark;

4. 'authorised representative' shall mean any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

5. 'importer' shall mean any natural or legal person established within the Community who places a product from a third country on the Community market;

6. 'distributor' shall mean any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;

7. 'economic operators' shall mean the manufacturer, the authorised representative, the importer and the distributor;

8. 'technical specification' shall mean a document that prescribes technical requirements to be fulfilled by a product, process or service;

9. 'harmonised standard' shall mean a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC on the basis of a request made by the Commission in accordance with Article 6 of that Directive;

10. 'accreditation' shall have the meaning assigned to it by Regulation (EC) No 765/2008;

11. 'national accreditation body' shall have the meaning assigned to it by Regulation (EC) No 765/2008;

12. 'conformity assessment' shall mean the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled;

13. 'conformity assessment body' shall mean a body that performs conformity assessment activities including calibration, testing, certification and inspection;

14. 'recall' shall mean any measure aimed at achieving the return of a product that has already been made available to the end user;

15. 'withdrawal' shall mean any measure aimed at preventing a product in the supply chain from being made available on the market;

16. 'CE marking' shall mean a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing;

17. 'Community harmonisation legislation' shall mean any Community legislation harmonising the conditions for the marketing of products.

Chapter R2

Obligations of economic operators

Article R2

Obligations of manufacturers

1. When placing their products on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in … [reference to the relevant part of the legislation].

2. Manufacturers shall draw up the required technical documentation and carry out the conformity assessment procedure applicable or have it carried out.

Where compliance of a product with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EC declaration of conformity and affix the conformity marking.

3. Manufacturers shall keep the technical documentation and the EC declaration of conformity for ... [period to be specified in proportion to the lifecycle of the product and the level of risk] after the product has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in product design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of a product is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by a product, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of marketed products, investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.

6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. The address must indicate a single point at which the manufacturer can be contacted.

7. Manufacturers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

8. Manufacturers who consider or have reason to believe that a product which they have placed on the market is not in conformity with the applicable Community harmonisation legislation shall immediately take the necessary corrective measures to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the product, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

Article R3

Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article [R2(1)] and the drawing up of technical documentation shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EC declaration of conformity and the technical documentation at the disposal of national surveillance authorities for … [period to be specified in proportion to the lifecycle of the product and the level of risk];

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a product;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by products covered by their mandate.

Article R4

Obligations of importers

1. Importers shall place only compliant products on the Community market.

2. Before placing a product on the market importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the product bears the required conformity marking or markings and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article [R2(5) and (6)].

Where an importer considers or has reason to believe that a product is not in conformity with … [reference to the relevant part of the legislation], he shall not place the product on the market until it has been brought into conformity. Furthermore, where the product presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product.

4. Importers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in … [reference to the relevant part of the legislation].

6. When deemed appropriate with regard to the risks presented by a product, importers shall, to protect the health and safety of consumers, carry out sample testing of marketed products, investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and shall keep distributors informed of such monitoring.

7. Importers who consider or have reason to believe that a product which they have placed on the market is not in conformity with the Community harmonisation legislation applicable shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8. Importers shall, for ... [period to be specified in proportion to the lifecycle of the product and the level of risk], keep a copy of the EC declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

Article R5

Obligations of distributors

1. When making a product available on the market distributors shall act with due care in relation to the requirements applicable.

2. Before making a product available on the market distributors shall verify that the product bears the required conformity marking or markings, that it is accompanied by the required documents and by instructions and safety information in a language which can be easily understood by consumers and other end-users in the Member State in which the product is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article [R2(5) and (6)] and Article [R4(3)].

Where a distributor considers or has reason to believe that a product is not in conformity with … [reference to the relevant part of the legislation], he shall not make the product available on the market until it has been brought into conformity. Furthermore, where the product presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in ... [reference to the relevant part of the legislation].

4. Distributors who consider or have reason to believe that a product which they have made available on the market is not in conformity with the Community harmonisation legislation applicable shall make sure that the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the product presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have made available on the market.

Article R6

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this ... [act] and he shall be subject to the obligations of the manufacturer under Article [R2], where he places a product on the market under his name or trademark or modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected.

Article R7

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities, for ... [period to be specified in proportion to the lifecycle of the product and the level of risk]:

(a) any economic operator who has supplied them with a product;

(b) any economic operator to whom they have supplied a product.

Chapter R3

Conformity of the product

Article R8

Presumption of conformity

Products which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the requirements covered by those standards or parts thereof, set out in … [reference to the relevant part of the legislation].

Article R9

Formal objection to a harmonised standard

1. When a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements which it covers and which are set out in … [reference to the relevant part of the legislation], the Commission or the Member State concerned shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC, giving its arguments. The Committee shall, having consulted the relevant European standardisation bodies, deliver its opinion without delay.

2. In the light of the Committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in or from the *Official Journal of the European Union*.

3. The Commission shall inform the European standardisation body concerned and, if necessary, request the revision of the harmonised standards concerned.

Article R10

EC declaration of conformity

1. The EC declaration of conformity shall state that the fulfilment of requirements specified in … [reference to relevant part of the legislation] has been demonstrated.

2. The EC declaration of conformity shall have the model structure set out in Annex III of Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, shall contain the elements specified in the relevant modules set out in Annex II of that Decision and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which market the product is placed or made available.

3. By drawing up the EC declaration of conformity, the manufacturer shall assume responsibility for the compliance of the product.

Article R11

General principles of the CE marking

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Article R12

Rules and conditions for affixing the CE marking

1. The CE marking shall be affixed visibly, legibly and indelibly to the product or to its data plate. Where that is not possible or not warranted on account of the nature of the product, it shall be affixed to the packaging and to the accompanying documents, where the legislation concerned provides for such documents.

2. The CE marking shall be affixed before the product is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

3. The CE marking shall be followed by the identification number of the notified body, where that body is involved in the production control phase.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

4. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and take appropriate action in the event of improper use of the marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.

Chapter R4

Notification of conformity assessment bodies

Article R13

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this ... [act].

Article R14

Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with the provisions of Article [R20].

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article [R15(1) to (6)]. In addition it shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article R15

Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article R16

Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article R17

Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under national law and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the product it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by … [reference to relevant part of the legislation] and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

It shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment activities shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of Community harmonisation legislation and of its implementing regulations;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the assessment personnel shall be guaranteed.

The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under … [reference to the relevant part of the legislation] or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Community harmonisation legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article R18

Presumption of conformity

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article [R17] in so far as the applicable harmonised standards cover those requirements.

Article R19

Formal objection to a harmonised standard

Where a Member State or the Commission has a formal objection to the harmonised standards referred to in Article [R18], the provisions of Article [R9] shall apply.

Article R20

Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article [R17] and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under … [reference to the relevant part of the legislation].

Article R21

Accredited in-house bodies

1. An accredited in-house body may be used to carry out conformity assessment activities for the undertaking of which it forms a part for the purpose of implementing the procedures set out in [Annex II — modules A1, A2, C1 or C2]. That body shall constitute a separate and distinct part of the undertaking and shall not participate in the design, production, supply, installation, use or maintenance of the products it assesses.

2. An accredited in-house body shall meet the following requirements:

(a) it shall be accredited in accordance with Regulation (EC) No 765/2008;

(b) the body and its personnel shall be organisationally identifiable and have reporting methods within the undertaking of which they form a part which ensure their impartiality and demonstrate it to the relevant national accreditation body;

(c) neither the body nor its personnel shall be responsible for the design, manufacture, supply, installation, operation or maintenance of the products they assess nor shall they engage in any activity that might conflict with their independence of judgment or integrity in relation to their assessment activities;

(d) the body shall supply its services exclusively to the undertaking of which it forms a part.

3. An accredited in-house body shall not be notified to the Member States or the Commission, but information concerning its accreditation shall be given by the undertaking of which it forms a part or by the national accreditation body to the notifying authority at the request of that authority.

Article R22

Application for notification

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. That application shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the product or products for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article [R17] of this ... [act].

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article [R17].

Article R23

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article [R17].

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and product or products concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate as referred to in Article [R22(2)], the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article [R17].

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this ... [act].

6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Article R24

Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Community acts.

2. The Commission shall make publicly available the list of the bodies notified under this ... [act], including the identification numbers that have been allocated to them and the activities for which they have been notified.

The Commission shall ensure that that list is kept up to date.

Article R25

Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article [R17], or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article R26

Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

Article R27

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in … [the relevant part of the legislation].

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the product with the provisions of this ... [act].

3. Where a notified body finds that requirements laid down in … [the relevant part of the legislation] or corresponding harmonised standards or technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a product no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

Article R28

Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:

(a) any refusal, restriction, suspension or withdrawal of a certificate;

(b) any circumstances affecting the scope of and conditions for notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this ... [act] carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article R29

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Article R30

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under … [the relevant act or other Community legislation] are put in place and properly operated in the form of a … [sectoral or cross sectoral] group or groups of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that or those group or groups, directly or by means of designated representatives.

Chapter R5

Safeguard procedures

Article R31

Procedure for dealing with products presenting a risk at national level

1. Where the market surveillance authorities of one Member State have taken action pursuant to Article 20 of Regulation (EC) No 765/2008, or where they have sufficient reason to believe that a product covered by this ... [act] presents a risk to the health or safety of persons or to other aspects of public interest protection covered by this ... [act], they shall

carry out an evaluation in relation to the product concerned covering all the requirements laid down in this ... [act]. The relevant economic operators shall cooperate as necessary with the market surveillance authorities.

Where, in the course of that evaluation, the market surveillance authorities find that the product does not comply with the requirements laid down in this ... [act], they shall without delay require the relevant economic operator to take all appropriate corrective action to bring the product into compliance with those requirements, to withdraw the product from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the products concerned that it has made available on the market throughout the Community.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the product's being made available on their national market, to withdraw the product from that market or to recall it.

They shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant product, the origin of the product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either:

(a) failure of the product to meet requirements relating to the health or safety of persons or to other aspects of public interest protection laid down in this ... [act]; or

(b) shortcomings in the harmonised standards referred to in … [reference to the relevant part of the legislation] conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the product concerned, and, in the event of disagreement with the notified national measure, of their objections.

7. Where, within …. [period to be specified] of receipt of the information referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures are taken in respect of the product concerned, such as withdrawal of the product from their market, without delay.

Article R32

Community safeguard procedure

1. Where, on completion of the procedure set out in Article [R31(3) and (4)], objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Community legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant product is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.

3. Where the national measure is considered justified and the non-compliance of the product is attributed to shortcomings in the harmonised standards referred to in [Article R31(5)(b)], the Commission shall inform the relevant European standardisation body or bodies and shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC. That Committee shall consult the relevant European standardisation body or bodies and deliver its opinion without delay.

Article R33

Compliant products which present a risk to health and safety

1. Where, having performed an evaluation under Article [R31(1)], a Member State finds that although a product is in compliance with this ... [act], it presents a risk to the health or safety of persons or to other aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the product concerned, when placed on the market, no longer presents that risk, to withdraw the product from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of all the products concerned that he has made available on the market throughout the Community.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not, and where necessary, propose appropriate measures.

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

Article R34

Formal non-compliance

1. Without prejudice to Article [R31], where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(a) the conformity marking has been affixed in violation of Article [R11] or of Article [R12];

(b) the conformity marking has not been affixed;

(c) the EC declaration of conformity has not been drawn up;

(d) the EC declaration of conformity has not been drawn up correctly;

(e) technical documentation is either not available or not complete.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or ensure that it is recalled or withdrawn from the market.

ANNEX II

CONFORMITY ASSESSMENT PROCEDURES

Module A

Internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain at least the following elements:

— a general description of the product,

— conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.

— descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

— a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

— results of design calculations made, examinations carried out, etc., and

— test reports.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the legislative instruments that apply to them.

4. Conformity marking and declaration of conformity

4.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument to each individual product that satisfies the applicable requirements of the legislative instrument.

4.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module A1

Internal production control plus supervised product testing

1. Internal production control plus supervised product testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4, and 5, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain, wherever applicable, at least the following elements:

— a general description of the product,

— conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.

— descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

— a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

— results of design calculations made, examinations carried out, etc., and

— test reports.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the legislative instruments that apply to them.

4. Product checks

For each individual product manufactured, one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his behalf, in order to verify conformity with the corresponding requirements of the legislative instrument. At the choice of the manufacturer, the tests are carried out either by an accredited in-house body or under the responsibility of a notified body chosen by the manufacturer.

Where the tests are carried out by a notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

5. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument to each individual product that satisfies the applicable requirements of the legislative instrument.

5.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. Authorised representative

The manufacturer's obligations set out in point 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module A2

Internal production control plus supervised product checks at random intervals

1. Internal production control plus supervised product checks at random intervals is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4, and 5, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain, wherever applicable, at least the following elements:

— a general description of the product,

— conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.

— descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

— a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

— results of design calculations made, examinations carried out, etc., and

— test reports.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the legislative instruments that apply to them.

4. Product checks

At the choice of the manufacturer, either an accredited in-house body or a notified body, chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks of the product, taking into account, *inter alia*, the technological complexity of the products and the quantity of production. An adequate sample of the final products, taken on site by the body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standard and/or technical specifications, or equivalent tests, shall be carried out to check the conformity of the product with the relevant requirements of the legislative instrument.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the product performs within acceptable limits, with a view to ensuring conformity of the product.

Where the tests are carried out by a notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

5. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument to each individual product that satisfies the applicable requirements of the legislative instrument.

5.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. Authorised representative

The manufacturer's obligations set out in point 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module B

EC-type examination

1. EC-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of the legislative instrument that apply to it.

2. EC-type examination may be carried out in either of the following manners:

— examination of a specimen, representative of the production envisaged, of the complete product (production type),

— assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the product (combination of production type and design type),

— assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

3. The manufacturer shall lodge an application for EC-type examination with a single notified body of his choice.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— a written declaration that the same application has not been lodged with any other notified body,

— the technical documentation. The technical documentation shall make it possible to assess the product's conformity with the applicable requirements of the legislative instrument and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain, wherever applicable, at least the following elements:

  — a general description of the product,

  — conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

  — descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

  — a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

  — results of design calculations made, examinations carried out, etc., and

  — test reports,

— the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme,

— the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall:

For the product:

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the product;

For the specimen(s):

4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications, these have been applied correctly;

4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential requirements of the legislative instrument;

4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of the specific legislative instrument that apply to the product concerned, the notified body shall issue an EC-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of the legislative instrument, the notified body shall refuse to issue an EC-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of the legislative instrument, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EC-type examination certificate of all modifications to the approved type that may affect the conformity of the product with the essential requirements of the legislative instrument or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EC-type examination certificate.

8. Each notified body shall inform its notifying authorities concerning the EC-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EC-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EC-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer shall keep a copy of the EC-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

Module C

Conformity to type based on internal production control

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the EC-type examination certificate and with the requirements of the legislative instrument that apply to them.

3. Conformity marking and declaration of conformity

3.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument to each individual product that is in conformity with the type described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

3.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module C1

Conformity to type based on internal production control plus supervised product testing

1. Conformity to type based on internal production control plus supervised product testing is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the type described in the EC-type examination certificate and with the requirements of the specific legislative instrument that apply to them.

3. Product checks

For each individual product manufactured one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his behalf, in order to verify conformity with the corresponding requirements of the legislative instrument. At the choice of the manufacturer, the tests shall be carried out either by an accredited in-house body or under the responsibility of a notified body, chosen by the manufacturer.

Where the tests are carried out by a notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

4. Conformity marking and declaration of conformity

4.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument to each individual product that is in conformity with the type described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

4.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module C2

Conformity to type based on internal production control plus supervised product checks at random intervals

1. Conformity to type based on internal production control plus supervised product checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the type described in the EC-type examination certificate and with the requirements of the specific legislative instrument that apply to them.

3. Product checks

At the choice of the manufacturer, either an accredited in-house body or a notified body, chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks on the product, taking into account, *inter alia*, the technological complexity of the products and the quantity of production. An adequate sample of the final products, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards and/or technical specifications, or equivalent tests, shall be carried out to check the conformity of the product with the relevant requirements of the legislative instrument. Where a sample does not conform to the acceptable quality level, the body shall take appropriate measures.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the product performs within acceptable limits, with a view to ensuring conformity of the product.

Where the tests are carried out by notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

4. Conformity marking and declaration of conformity

4.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument to each individual product that is in conformity with the type described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

4.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module D

Conformity to type based on quality assurance of the production process

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the products concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the products concerned.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— a written declaration that the same application has not been lodged with any other notified body,

— all relevant information for the product category envisaged,

— the documentation concerning the quality system,

— the technical documentation of the approved type and a copy of the EC-type examination certificate.

3.2. The quality system shall ensure that the products are in conformity with the type described in the EC-type examination certificate and comply with the requirements of the legislative instrument that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

— the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

— the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and

— the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specifications.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, fifth indent, to verify the manufacturer's ability to identify the relevant requirements of the legislative instrument and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

— the quality system documentation,

— the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that is in conformity with the type described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

— the documentation referred to in point 3.1,

— the change referred to in point 3.5, as approved,

— the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module D1

Quality assurance of the production process

1. Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain at least the following elements:

— a general description of the product,

— conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

— a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

— results of design calculations made, examinations carried out, etc., and

— test reports.

3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the product has been placed on the market.

4. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the products concerned as specified in point 5, and shall be subject to surveillance as specified in point 6.

5. Quality system

5.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the products concerned.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— a written declaration that the same application has not been lodged with any other notified body,

— all relevant information for the product category envisaged,

— the documentation concerning the quality system,

— the technical documentation referred to in point 2.

5.2. The quality system shall ensure compliance of the products with the requirements of the legislative instrument that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

— the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

— the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.,

— the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of the legislative instrument and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.2 or whether reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

6. Surveillance under the responsibility of the notified body

6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

— the quality system documentation,

— the technical documentation referred to in point 2,

— the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

6.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

7. Conformity marking and declaration of conformity

7.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 5.1, the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument.

7.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

8. The manufacturer shall, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

— the documentation referred to in point 5.1,

— the change referred to in point 5.5, as approved,

— the decisions and reports of the notified body referred to in points 5.5, 6.3 and 6.4.

9. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

10. Authorised representative

The manufacturer's obligations set out in points 3, 5.1, 5.5, 7 and 8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module E

Conformity to type based on product quality assurance

1. Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for final product inspection and testing of the products concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the products concerned.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— a written declaration that the same application has not been lodged with any other notified body,

— all relevant information for the product category envisaged,

— the documentation concerning the quality system, and

— the technical documentation of the approved type and a copy of the EC-type examination certificate.

3.2. The quality system shall ensure compliance of the products with the type described in the EC-type examination certificate and with the applicable requirements of the legislative instrument.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,

— the examinations and tests that will be carried out after manufacture,

— the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.,

— the means of monitoring the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, fifth indent, in order to verify the manufacturer's ability to identify the relevant requirements of the legislative instrument and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

— the quality system documentation,

— the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that is in conformity with the type described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

— the documentation referred to in point 3.1,

— the change referred to in point 3.5, as approved,

— the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module E1

Quality assurance of final product inspection and testing

1. Quality assurance of final product inspection and testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain at least the following elements:

— a general description of the product,

— conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

— a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

— results of design calculations made, examinations carried out, etc., and

— test reports.

3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the product has been placed on the market.

4. Manufacturing

The manufacturer shall operate an approved quality system for final product inspection and testing of the products concerned as specified in point 5 and shall be subject to surveillance as specified in point 6.

5. Quality system

5.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the products concerned.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— a written declaration that the same application has not been lodged with any other notified body,

— all relevant information for the product category envisaged,

— the documentation concerning the quality system, and

— the technical documentation referred to in point 2.

5.2. The quality system shall ensure compliance of the products with the requirements of the legislative instrument that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,

— the examinations and tests that will be carried out after manufacture,

— the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.,

— the means of monitoring the effective operation of the quality system.

5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of the legislative instrument and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

6. Surveillance under the responsibility of the notified body

6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

— the quality system documentation,

— the technical documentation referred to in point 2,

— the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

6.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

7. Conformity marking and declaration of conformity

7.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 5.1, the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument.

7.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

8. The manufacturer shall, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

— the documentation referred to in point 5.1,

— the change referred to in point 5.5, as approved,

— the decisions and reports of the notified body referred to in points 5.5, 6.3 and 6.4.

9. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

10. Authorised representative

The manufacturer's obligations set out in points 3, 5.1, 5.5, 7 and 8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module F

Conformity to type based on product verification

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5.1 and 6, and ensures and declares on his sole responsibility that the products concerned, which have been subject to the provisions of point 3, are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the EC-type examination certificate and with the requirements of the legislative instrument that apply to them.

3. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the products with the approved type described in the EC-type examination certificate and with the appropriate requirements of the legislative instrument.

The examinations and tests to check the conformity of the products with the appropriate requirements shall be carried out, at the choice of the manufacturer either by examination and testing of every product as specified in point 4 or by examination and testing of the products on a statistical basis as specified in point 5.

4. Verification of conformity by examination and testing of every product

4.1. All products shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or technical specifications, or equivalent tests, shall be carried out in order to verify conformity with the approved type described in the EC-type examination certificate and with the appropriate requirements of the legislative instrument. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the product has been placed on the market.

5. Statistical verification of conformity

5.1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present his products for verification in the form of homogeneous lots.

5.2. A random sample shall be taken from each lot according to the requirements of the legislative instrument. All products in a sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or technical specifications, or equivalent tests, shall be carried out in order to ensure their conformity with the applicable requirements of the legislative instrument and to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

5.3. If a lot is accepted, all products of the lot shall be considered approved, except for those products from the sample that have been found not to satisfy the tests.

The notified body shall issue a certificate of conformity in respect to the examinations and tests carried out, and shall affix its identification number to each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the product has been placed on the market.

5.4. If a lot is rejected, the notified body or the competent authority shall take appropriate measures to prevent that lot's being placed on the market. In the event of the frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures.

6. Conformity marking and declaration of conformity

6.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual product that is in conformity with the approved type described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

6.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities, for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

If the notified body referred to in point 3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the products.

7. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the products during the manufacturing process.

8. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 2 and 5.1.

Module F1

Conformity based on product verification

1. Conformity based on product verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 6.1 and 7 and ensures and declares on his sole responsibility that the products concerned, which have been subject to the provisions of point 4, are in conformity with the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain at least the following elements:

— a general description of the product,

— conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

— a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

— results of design calculations made, examinations carried out, etc., and

— test reports.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the product has been placed on the market.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the applicable requirements of the legislative instrument.

4. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests to check the conformity of the products with the applicable requirements of the legislative instrument.

The examinations and tests to check the conformity with those requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every product as specified in point 5, or by examination and testing of the products on a statistical basis as specified in point 6.

5. Verification of conformity by examination and testing of every product

5.1. All products shall be individually examined and appropriate tests, set out in the relevant harmonised standards and/or technical specifications, or equivalent tests, shall be carried out to verify conformity with the requirements that apply to them. In the absence of such a harmonised standard and/or technical specification the notified body concerned shall decide on the appropriate tests to be carried out.

5.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the product has been placed on the market.

6. Statistical verification of conformity

6.1. The manufacturer shall take all measures necessary so that the manufacturing process ensures the homogeneity of each lot produced, and shall present his products for verification in the form of homogeneous lots.

6.2. A random sample shall be taken from each lot according to the requirements of the legislative instrument. All products in the sample shall be individually examined and appropriate tests set out in the relevant harmonised standards and/or technical specifications, or equivalent tests, to establish conformity with the requirements that apply to them, shall be carried out to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard and/or technical specification the notified body concerned shall decide on the appropriate tests to be carried out.

6.3. If a lot is accepted, all products of the lot shall be considered approved, except for those products from the sample that have been found not to satisfy the tests.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the product has been placed on the market.

If a lot is rejected, the notified body shall take appropriate measures to prevent that lot being placed on the market. In the event of the frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures.

7. Conformity marking and declaration of conformity

7.1. The manufacturer shall affix the conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument.

7.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

If the notified body referred to in point 5 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the products.

8. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the products during the manufacturing process.

9. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 3 and 6.1.

Module G

Conformity based on unit verification

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his sole responsibility that the product concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of the legislative instrument that apply to it.

2. Technical documentation

The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain at least the following elements:

— a general description of the product,

— conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

— a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

— results of design calculations made, examinations carried out, etc., and

— test reports.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the product has been placed on the market.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with the applicable requirements of the legislative instrument.

4. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or technical specifications, or equivalent tests, to check the conformity of the product with the applicable requirements of the legislative instrument, or have them carried out. In the absence of such a harmonised standard and/or technical specification the notified body concerned shall decide on the appropriate tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved product, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the product has been placed on the market.

5. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each product that satisfies the applicable requirements of the legislative instrument.

5.2. The manufacturer shall draw up a written declaration of conformity and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. Authorised representative

The manufacturer's obligations set out in points 2 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module H

Conformity based on full quality assurance

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the products concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the products concerned.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— the technical documentation for one model of each category of products intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements:

  — a general description of the product,

  — conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

  — descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

  — a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

  — results of design calculations made, examinations carried out, etc.,

  — test reports,

— the documentation concerning the quality system, and

— a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the products with the requirements of the legislative instrument that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,

— the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the essential requirements of the legislative instrument that apply to the products will be met,

— the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered,

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

— the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

— the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.,

— the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, second indent, to verify the manufacturer's ability to identify the applicable requirements of the legislative instrument and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The manufacturer or his authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

— the quality system documentation,

— the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.,

— the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

— the technical documentation referred to in point 3.1,

— the documentation concerning the quality system referred to in point 3.1,

— the change referred to in point 3.5, as approved,

— the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module H1

Conformity based on full quality assurance plus design examination

1. Conformity based on full quality assurance plus design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 6, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the products concerned as specified in point 3 and shall be subject to surveillance as specified in point 5. The adequacy of the technical design of the products shall have been examined in accordance with point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the products concerned.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— all relevant information for the product category envisaged,

— the documentation concerning the quality system,

— a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the products with the requirements of the legislative instrument that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,

— the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the essential requirements of the legislative instrument that apply to the products will be met,

— the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered,

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

— the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

— the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.,

— the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specifications.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises.

The manufacturer or his authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.6. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

4. Design examination

4.1. The manufacturer shall lodge an application for examination of the design with the notified body referred to in point 3.1.

4.2. The application shall make it possible to understand the design, manufacture and operation of the product, and to assess the conformity with the requirements of the legislative instrument that apply to it. It shall include:

— the name and address of the manufacturer,

— a written declaration that the same application has not been lodged with any other notified body,

— the technical documentation. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design and operation of the product. The technical documentation shall, wherever applicable, contain at least the following elements:

— a general description of the product,

— conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

— a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

— results of design calculations made, examinations carried out, etc., and

— test reports,

— the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full, and shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4.3. The notified body shall examine the application, and where the design meets the requirements of the legislative instrument that apply to the product it shall issue an EC design examination certificate to the manufacturer. The certificate shall give the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined design to be evaluated, and to allow for in-service control, where applicable.

Where the design does not satisfy the applicable requirements of the legislative instrument, the notified body shall refuse to issue a design examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

4.4. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved design may no longer comply with the applicable requirements of the legislative instrument, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall keep the notified body that has issued the EC design examination certificate informed of any modification to the approved design that may affect the conformity with the essential requirements of the legislative instrument or the conditions for validity of the certificate. Such modifications shall require additional approval — from the notified body that issued the EC design examination certificate — in the form of an addition to the original EC design examination certificate.

4.5. Each notified body shall inform its notifying authorities of the EC design examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of the EC design examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC design examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and of the results of the examinations carried out by the notified body.

The notified body shall keep a copy of the EC design examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer until the expiry of the validity of the certificate.

4.6. The manufacturer shall keep a copy of the EC design examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market.

5. Surveillance under the responsibility of the notified body

5.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

5.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

— the quality system documentation,

— the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.,

— the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

5.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

5.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

6. Conformity marking and declaration of conformity

6.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument.

6.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up and shall mention the number of the design examination certificate.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

7. The manufacturer shall, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

— the documentation concerning the quality system referred to in point 3.1,

— the change referred to in point 3.5, as approved,

— the decisions and reports of the notified body referred to in points 3.5, 5.3 and 5.4.

8. Authorised representative

The manufacturer's authorised representative may lodge the application referred to in points 4.1 and 4.2 and fulfil the obligations set out in points 3.1, 3.5, 4.4, 4.6, 6 and 7, on his behalf and under his responsibility, provided that they are specified in the mandate.

TABLE: CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION

DESIGN

A. Internal production control	B. Type examination	G. Unit verification	H. Full quality assurance
Manufacturer — keeps technical documentation at the disposal of national authorities	Manufacturer submits to notified body — technical documentation — supporting evidence for the adequacy of the technical design solution — specimen(s), representative of the production envisaged, as required Notified body — ascertains conformity with essential requirements — examines technical documentation and supporting evidence to assess adequacy of the technical design — for specimen(s): carries out tests, if necessary — issues EC-type examination certificate	Manufacturer — submits technical documentation	EN ISO 9001:2000 [4] Manufacturer — operates an approved quality system for design — submits technical documentation Notified body — carries out surveillance of the QS **H1** Notified body — verifies conformity of design [1] — issues EC-design examination certificate [1]

PRODUCTION

	C. Conformity to type	D. Production quality assurance	E. Product quality assurance	F. Product verification		
A. Manufacturer — declares conformity with essential requirements — affixes required conformity marking	**C.** Manufacturer — declares conformity with approved type — affixes required conformity marking	EN ISO 9001:2000 ([2]) Manufacturer — operates an approved quality system for production, final inspection and testing — declares conformity with approved type — affixes required conformity marking	EN ISO 9001:2000 ([3]) Manufacturer — operates an approved quality system for final inspection and testing — declares conformity with approved type — affixes required conformity marking	Manufacturer — declares conformity with approved type — affixes required conformity marking	Manufacturer — submits product — declares conformity — aAffixes required conformity marking	Manufacturer — operates an approved QS for production, final inspection and testing — declares conformity — affixes required conformity marking
A1. Accredited in-house body or notified body — tests on specific aspects of the product ([1])	**C1.** Accredited in-house body or notified body — tests on specific aspects of the product ([1])	**D1.** declares conformity to essential requirements — affixes required conformity marking	**E1.** declares conformity to essential requirements — affixes required conformity marking	**F1.** declares conformity to essential requirements — affixes required conformity marking		
		Notified body — approves the QS — carries out surveillance of the QS	Notified body — approves the QS — carries out surveillance of the QS	Notified body — verifies conformity to essential requirements — issues certificate of conformity	Notified body — verifies conformity to essential requirements — issues certificate of conformity	Notified body — carries out surveillance of the QS
A2. — Product checks at random intervals ([1])	**C2.** — Product checks at random intervals ([1])					

([1]) Supplementary requirements which may be used in sectoral legislation.
([2]) Except for subclause 7.3 and requirements relating to customer satisfaction and continual improvement.
([3]) Except for subclauses 7.1, 7.2.3, 7.3, 7.4, 7.5.1, 7.5.2, 7.5.3 and requirements relating to customer satisfaction and continual improvement.
([4]) Except for requirements relating to customer satisfaction and continual improvement.

ANNEX III

EC DECLARATION OF CONFORMITY

1. No … (unique identification of the product):

2. Name and address of the manufacturer or his authorised representative:

3. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):

4. Object of the declaration (identification of product allowing traceability. It may include a photograph, where appropriate):

5. The object of the declaration described above is in conformity with the relevant Community harmonisation legislation: .....

6. References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:

7. Where applicable, the notified body ... (name, number) … performed … (description of intervention) … and issued the certificate: …

8. Additional information:

Signed for and on behalf of: .....

(place and date of issue):

(name, function) (signature):

III

(Acts adopted under the EU Treaty)

ACTS ADOPTED UNDER TITLE VI OF THE EU TREATY

COUNCIL DECISION 2008/633/JHA

of 23 June 2008

concerning access for consultation of the Visa Information System (VIS) by designated authorities of Member States and by Europol for the purposes of the prevention, detection and investigation of terrorist offences and of other serious criminal offences

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 30(1)(b) and Article 34(2)(c) thereof,

Having regard to the proposal from the Commission,

Having regard to the Opinion of the European Parliament,

Whereas:

(1) Council Decision 2004/512/EC of 8 June 2004 establishing the Visa Information System (VIS) [1] established the VIS as a system for the exchange of visa data between Member States. The establishment of the VIS represents one of the key initiatives within the policies of the European Union aimed at establishing an area of freedom, security and justice. The VIS should have the purpose of improving the implementation of the common visa policy and should also contribute towards internal security and to combating terrorism under clearly defined and monitored circumstances.

(2) During its meeting of 7 March 2005 the Council adopted conclusions stating that 'in order to achieve fully the aim of improving internal security and the fight against terrorism', Member State authorities responsible for internal security should be guaranteed access to the VIS, 'in the course of their duties in relation to the prevention, detection and investigation of criminal offences, including terrorist acts and threats', 'subject to strict compliance with the rules governing the protection of personal data'.

(3) It is essential in the fight against terrorism and other serious crimes for the relevant services to have the fullest and most up-to-date information in their respective fields. The Member States' competent national services need information if they are to perform their tasks. The information contained in the VIS may be necessary for the purposes of preventing and combating terrorism and serious crimes and should therefore be available, subject to the conditions set out in this Decision, for consultation by the designated authorities.

(4) Moreover, the European Council has stated that Europol has a key role with respect to cooperation between Member States' authorities in the field of cross-border crime investigation in supporting Union-wide crime prevention, analyses and investigation. Consequently, Europol should also have access to VIS data within the framework of its tasks and in accordance with the Convention of 26 July 1995 on the Establishment of a European Police Office [2].

(5) This Decision complements Regulation (EC) No 767/2008 of the European Parliament and of the Council of 9 July 2008 concerning the Visa Information System (VIS) and the exchange of data between Member States on 7 stay-visas (VIS Regulation) [3] insofar as it provides for a legal base under Title VI of the Treaty on European Union authorising access to the VIS for designated authorities and for Europol.

[1] OJ L 213, 15.6.2004, p. 5.

[2] OJ C 316, 27.11.1995, p. 2. Convention as last amended by the Protocol amending that Convention (OJ C 2, 6.1.2004, p. 3).

[3] See page 60 of this Official Journal.

(6) It is necessary to designate the competent Member States' authorities as well as the central access points through which access is done and to keep a list of the operating units within the designated authorities that are authorised to access the VIS for the specific purposes of the prevention, detection and investigation of terrorist offences and other serious criminal offences as referred to in Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States ([1]). It is essential to ensure that the duly empowered staff with a right to access the VIS is limited to those who 'have a need to know' and possess appropriate knowledge about data security and data protection rules.

(7) Requests for access to the VIS should be made by the operating units within the designated authorities to the central access points. These central access points should then process the requests for access to the VIS following a verification whether all conditions for access are fulfilled. In an exceptional case of urgency the central access points should process the request immediately and only do the verification afterwards.

(8) For the purposes of protection of personal data, and in particular to exclude routine access, the processing of VIS data should only be on a case-by-case basis. Such a specific case exists in particular when the access for consultation is connected to a specific event or to a danger associated with serious crime, or to (a) specific person(s) in respect of whom there are serious grounds for believing that the person(s) will commit or has (have) committed terrorist offences or other serious criminal offences or that the person(s) has (have) a relevant connection with such (a) person(s). The designated authorities and Europol should thus only search data contained in the VIS when they have reasonable grounds to believe that such a search will provide information that will substantially assist them in preventing, detecting or investigating serious crime.

(9) Once the proposed Framework Decision on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters has entered into force it should apply to the personal data which are processed pursuant to this Decision. However, until the rules set out in that Framework Decision are applicable and in order to supplement them, adequate provisions have to be provided for to ensure the necessary data protection. Each Member State should ensure an adequate data protection level in its national law which at least corresponds to that resulting from the Council of Europe Convention of 28 January 1981 for the Protection of Individuals with regard to Automatic Processing of Personal Data and the corresponding case law pursuant to Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms and, for those Member States which have ratified it, the Additional Protocol of 8 November 2001 to that Convention, and should take into account Recommendation No R (87) 15 of 17 September 1987 of the Committee of Ministers of the Council of Europe Regulating the Use of Personal Data in the Police Sector.

(10) The effective monitoring of the application of this Decision should be evaluated at regular intervals.

(11) Since the objectives of this Decision, namely the creation of obligations and conditions for access for consultation of VIS data by Member States' designated authorities and by Europol, cannot be sufficiently achieved by the Member States and can, therefore, by reason of the scale and effects of the action, be better achieved at the level of the European Union, the Council may adopt measures in accordance with the principle of subsidiarity, referred to in Article 2 of the Treaty on European Union and defined in Article 5 of the Treaty establishing the European Community. In accordance with the principle of proportionality, as set out in that Article, this Decision does not go beyond what is necessary in order to achieve those objectives.

(12) In accordance with Article 47 of the Treaty on European Union, this Decision does not affect the competences of the European Community, in particular as exercised in Regulation (EC) No 767/2008 and in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ([2]).

(13) This Decision constitutes a development of provisions of the Schengen *acquis* in which the United Kingdom does not take part in accordance with Council Decision 2000/365/EC of 29 May 2000 concerning the request of the United Kingdom of Great Britain and Northern Ireland to take part in some of the provisions of the Schengen *acquis* ([3]). The United Kingdom is therefore not taking part in its adoption and is not bound by it or subject to its application.

(14) This Decision constitutes a development of provisions of the Schengen *acquis* in which Ireland does not take part in accordance with Council Decision 2002/192/EC of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* ([4]). Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application.

([1]) OJ L 190, 18.7.2002, p. 1.

([2]) OJ L 281, 23.11.1995, p. 31. Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

([3]) OJ L 131, 1.6.2000, p. 43.

([4]) OJ L 64, 7.3.2002, p. 20.

(15) However, in accordance with Council Framework Decision 2006/960/JHA of 18 December 2006 on simplifying the exchange of information and intelligence between law enforcement authorities of the Member States of the European Union ([1]), information contained in the VIS can be provided to the United Kingdom and Ireland by the competent authorities of the Member States whose designated authorities have access to the VIS pursuant to this Decision. Information held in the national visa registers of the United Kingdom and Ireland can be provided to the competent law enforcement authorities of the other Member States. Any form of direct access for central authorities of the United Kingdom and Ireland to the VIS would, under the present state of their participation in the Schengen *acquis*, require an agreement between the Community and those Member States, possibly to be supplemented by other rules specifying the conditions and procedures for such access.

(16) As regards Iceland and Norway, this Decision constitutes, with the exception of Article 7, a development of provisions of the Schengen *acquis* within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen *acquis* ([2]) which fall within the area referred to in Article 1, point B of Council Decision 1999/437/EC ([3]) on certain arrangements for the application of that Agreement.

(17) As regards Switzerland, this Decision constitutes, with the exception of Article 7, a development of the provisions of the Schengen *acquis* within the meaning of the Agreement signed by the European Union, the European Community and the Swiss Confederation concerning the association of the Swiss Confederation with the implementation, application and development of the Schengen *acquis* which fall within the area referred to in Article 1, point B of Decision 1999/437/EC read in conjunction with Article 4(1) of Council Decision 2004/849/EC ([4]).

(18) This Decision, save Article 6, constitutes an act building on the Schengen *acquis* or otherwise related to it within the meaning of Article 3(2) of the 2003 Act of Accession and Article 4(2) of the 2005 Act of Accession.

(19) This Decision respects the fundamental rights and observes the principles reflected in particular in the Charter of Fundamental Rights of the European Union,

([1]) OJ L 386, 18.12.2006, p. 89.

([2]) OJ L 176, 10.7.1999, p. 36.

([3]) OJ L 176, 10.7.1999, p. 31.

([4]) Decision 2004/849/EC of 25 October 2004 on the signing, on behalf of the European Union, and on the provisional application of certain provisions of the Agreement between the European Union, the European Community and the Swiss Confederation concerning the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* (OJ L 368, 15.12.2004, p. 26).

HAS DECIDED AS FOLLOWS:

Article 1

Subject matter and scope

This Decision lays down the conditions under which Member States' designated authorities and the European Police Office (Europol) may obtain access for consultation of the Visa Information System (VIS) for the purposes of the prevention, detection and investigation of terrorist offences and of other serious criminal offences.

Article 2

Definitions

1. For the purposes of this Decision, the following definitions shall apply:

(a) 'Visa Information System (VIS)' means the Visa Information System as established by Decision 2004/512/EC;

(b) 'Europol' means the European Police Office as established by the Convention of 26 July 1995 on the Establishment of a European Police Office (the Europol Convention);

(c) 'terrorist offences' means the offences under national law which correspond or are equivalent to the offences in Articles 1 to 4 of Council Framework Decision 2002/475/JHA of 13 June 2002 on combating terrorism ([5]);

(d) 'serious criminal offences' means the forms of crime which correspond or are equivalent to those referred to in Article 2(2) of Framework Decision 2002/584/JHA;

(e) 'designated authorities' means authorities which are responsible for the prevention, detection or investigation of terrorist offences or of other serious criminal offences and designated by the Member States pursuant to Article 3.

2. The definitions in Regulation (EC) No 767/2008 shall also apply.

Article 3

Designated authorities and central access points

1. Member States shall designate the authorities referred to in Article 2(1)(e) which are authorised to access VIS data pursuant to this Decision.

2. Every Member State shall keep a list of the designated authorities. By 2 December 2008 every Member State shall notify in a declaration to the Commission and the General Secretariat of the Council their designated authorities and may at any time amend or replace its declaration by another declaration.

([5]) OJ L 164, 22.6.2002, p. 3.

3. Every Member State shall designate the central access point(s) through which the access is done. Member States may designate more than one central access point to reflect their organisational and administrative structure in fulfilment of their constitutional or legal requirements. By 2 December 2008 every Member State shall notify in a declaration to the Commission and the General Secretariat of the Council their central access point(s) and may at any time amend or replace its declaration by another declaration.

4. The Commission shall publish the declarations referred to in paragraphs 2 and 3 in the *Official Journal of the European Union*.

5. At national level, each Member State shall keep a list of the operating units within the designated authorities that are authorised to access the VIS through the central access point(s).

6. Only duly empowered staff of the operational units as well as the central access point(s) shall be authorised to access the VIS in accordance with Article 4.

Article 4

Procedure for access to the VIS

1. Where the conditions of Article 5 are fulfilled the operating units referred to in Article 3(5) shall submit a reasoned written or electronic request to the central access points referred to in Article 3(3) to access the VIS. Upon receipt of a request for access the central access point(s) shall verify whether the conditions for access referred to in Article 5 are fulfilled. If all conditions for access are fulfilled, the duly authorised staff of the central access point(s) shall process the requests. The VIS data accessed shall be transmitted to the operating units referred to in Article 3(5) in such a way as not to compromise the security of the data.

2. In an exceptional case of urgency, the central access point(s) may receive written, electronic or oral requests. In such cases, the central access point(s) shall process the request immediately and only verify *ex-post* whether all the conditions of Article 5 are fulfilled, including whether an exceptional case of urgency existed. The *ex-post* verification shall take place without undue delay after the processing of the request.

Article 5

Conditions for access to VIS data by designated authorities of Member States

1. Access to the VIS for consultation by designated authorities shall take place within the scope of their powers and if the following conditions are met:

(a) access for consultation must be necessary for the purpose of the prevention, detection or investigation of terrorist offences or other serious criminal offences;

(b) access for consultation must be necessary in a specific case;

(c) there are reasonable grounds to consider that consultation of VIS data will substantially contribute to the prevention, detection or investigation of any of the criminal offences in question.

2. Consultation of the VIS shall be limited to searching with any of the following VIS data in the application file:

(a) surname, surname at birth (former surname(s)); first name(s); sex; date, place and country of birth;

(b) current nationality and nationality at birth;

(c) type and number of the travel document, the authority which issued it and the date of issue and of expiry;

(d) main destination and duration of the intended stay;

(e) purpose of travel;

(f) intended date of arrival and departure;

(g) intended border of first entry or transit route;

(h) residence;

(i) fingerprints;

(j) type of visa and the number of the visa sticker;

(k) details of the person issuing an invitation and/or liable to pay the applicant's subsistence costs during the stay.

3. Consultation of the VIS shall, in the event of a hit, give access to all of the data listed in paragraph 2 as well as to:

(a) any other data taken from the application form;

(b) photographs;

(c) the data entered in respect of any visa issued, refused, annulled, revoked or extended.

Article 6

Conditions for access to VIS data by designated authorities of a Member State in respect of which Regulation (EC) No 767/2008 has not yet been put into effect

1. Access to the VIS for consultation by designated authorities of a Member State in respect of which Regulation (EC) No 767/2008 has not yet been put into effect shall take place within the scope of their powers and

(a) subject to the same conditions as referred to in Article 5(1); and

(b) by a duly motivated written or electronic request to a designated authority of a Member State to which Regulation (EC) No 767/2008 applies; that authority shall then request the national central access point(s) to consult the VIS.

2. A Member State in respect of which Regulation (EC) No 767/2008 has not yet been put into effect shall make its visa information available to Member States to which Regulation (EC) No 767/2008 applies, on the basis of a duly reasoned written or electronic request, subject to compliance with the conditions laid down in Article 5(1).

3. Article 8(1) and (3) to (6), Article 9(1), Article 10(1) and (3), Article 12, Article 13(1) and (3) shall apply accordingly.

Article 7

Conditions for access to VIS data by Europol

1. Access to the VIS for consultation by Europol shall take place within the limits of its mandate and:

(a) when necessary for the performance of its tasks pursuant to Article 3(1), point 2 of the Europol Convention and for the purposes of a specific analysis as referred to in Article 10 of the Europol Convention; or

(b) when necessary for the performance of its tasks pursuant to Article 3(1), point 2 of the Europol Convention and for an analysis of a general nature and of a strategic type, as referred to in Article 10 of the Europol Convention, provided that VIS data is rendered anonymous by Europol prior to such processing and retained in a form in which identification of the data subjects is no longer possible.

2. Article 5(2) and (3) shall apply accordingly.

3. Europol shall designate a specialised unit for the purpose of this Decision with duly empowered Europol officials to act as the central access point to access the VIS for consultation.

4. Processing of information obtained by Europol from access to the VIS shall be subject to the consent of the Member State which has entered that data in the VIS. Such consent shall be obtained via the Europol national unit of that Member State.

Article 8

Protection of personal data

1. The processing of personal data consulted under this Decision shall be subject to the following rules and to the national law of the consulting Member State. With regard to the processing of personal data consulted under this Decision, each Member State shall ensure an adequate data protection level in its national law which at least corresponds to that resulting from the Council of Europe Convention of 28 January 1981 for the Protection of Individuals with regard to Automatic Processing of Personal Data and, for those Member States which have ratified it, the Additional Protocol of 8 November 2001 to that Convention, and shall take into account Recommendation No R (87)15 of 17 September 1987 of the Committee of Ministers of the Council of Europe Regulating the Use of Personal Data in the Police Sector.

2. The processing of personal data by Europol pursuant to this Decision shall be in accordance with the Europol Convention and the rules adopted in implementation thereof and supervised by the independent joint supervisory body established by Article 24 of the Convention.

3. Personal data obtained pursuant to this Decision from the VIS shall only be processed for the purposes of the prevention, detection, investigation and prosecution of terrorist offences or other serious criminal offences.

4. Personal data obtained pursuant to this Decision from the VIS shall not be transferred or made available to a third country or to an international organisation. However, in an exceptional case of urgency such data may be transferred or made available to a third country or an international organisation, exclusively for the purposes of the prevention and detection of terrorist offences and of other serious criminal offences and under the conditions set out in Article 5(1) of this Decision, subject to the consent of the Member State having entered the data into the VIS and in accordance with the national law of the Member State transferring the data or making them available. In accordance with national law, Member States shall ensure that records are kept of such transfers and make them available to national data protection authorities on request. The transfer of data by the Member State that entered the data in the VIS according to Regulation (EC) No 767/2008 shall be subject to the national law of that Member State.

5. The competent body or bodies which, in accordance with national law, are charged with the supervision of the processing of personal data by the authorities designated under this Decision shall monitor the lawfulness of the processing of personal data pursuant to this Decision. The Member States shall ensure that these bodies have sufficient resources to fulfil the tasks entrusted to them under this Decision.

6. The bodies referred to in paragraph 5 shall ensure that at least every four years an audit of the processing of personal data pursuant to this Decision is carried out, where applicable according to international auditing standards.

7. Member States and Europol shall allow the competent body or bodies referred to in paragraphs 2 and 5 to obtain the necessary information to enable them to carry out their tasks in accordance with this Article.

8. Before being authorised to process data stored in the VIS, the staff of the authorities having a right to access the VIS shall receive appropriate training about data security and data protection rules and shall be informed of any relevant criminal offences and penalties.

Article 9

Data security

1. The Member State responsible shall ensure the security of the data during transmission to the designated authorities and when received by them.

2. Each Member State shall adopt the necessary security measures with respect to data to be retrieved from the VIS pursuant to this Decision and to be subsequently stored, in particular in order to:

(a) physically protect data, including by making contingency plans for the protection of critical infrastructure;

(b) deny unauthorised persons access to national installations in which the Member State stores data (checks at entrance to the installation);

(c) prevent the unauthorised reading, copying, modification or removal of data media (data media control);

(d) prevent the unauthorised inspection, modification or deletion of stored personal data (storage control);

(e) prevent the unauthorised processing of data from the VIS (control of data processing);

(f) ensure that persons authorised to access the VIS have access only to the data covered by their access authorisation, by means of individual and unique user identities and confidential access modes only (data access control);

(g) ensure that all authorities with a right of access to the VIS create profiles describing the functions and responsibilities of persons who are authorised to access and search the data and make these profiles available to the national supervisory authorities referred to in Article 8(5) without delay upon their request (personnel profiles);

(h) ensure that it is possible to verify and establish to which bodies personal data may be transmitted using data communication equipment (communication control);

(i) ensure that it is possible to verify and establish what data has been retrieved from the VIS, when, by whom and for what purpose (control of data recording);

(j) prevent the unauthorised reading and copying of personal data during their transmission from the VIS, in particular by means of appropriate encryption techniques (transport control);

(k) monitor the effectiveness of the security measures referred to in this paragraph and take the necessary organisational measures related to internal monitoring to ensure compliance with this Decision (self-auditing).

Article 10

Liability

1. Any person who, or Member State which, has suffered damage as a result of an unlawful processing operation or any act incompatible with this Decision shall be entitled to receive compensation from the Member State which is responsible for the damage suffered. That Member State shall be exempted from its liability, in whole or in part, if it proves that it is not responsible for the event giving rise to the damage.

2. If any failure of a Member State to comply with its obligations under this Decision causes damage to the VIS, that Member State shall be held liable for such damage, unless and insofar as another Member State failed to take reasonable measures to prevent the damage from occurring or to minimise its impact.

3. Claims for compensation against a Member State for the damage referred to in paragraphs 1 and 2 shall be governed by the provisions of national law of the defendant Member State.

Article 11

Self-monitoring

Member States shall ensure that each authority entitled to access VIS data takes the measures necessary to comply with this Decision and cooperates, where necessary, with the national body or bodies referred to in Article 8(5).

Article 12

Penalties

Member States shall take the necessary measures to ensure that any use of VIS data contrary to the provisions of this Decision is punishable by penalties, including administrative and/or criminal penalties, that are effective, proportionate and dissuasive.

Article 13

Keeping of VIS data in national files

1. Data retrieved from the VIS may be kept in national files only when necessary in an individual case in accordance with the purposes set out in this Decision and in accordance with the relevant legal provisions including those concerning data protection and for no longer than necessary in the individual case.

2. Paragraph 1 shall not prejudice the provisions of national law of a Member State concerning the entry by its designated authorities in their national files of data which that Member State entered in the VIS according to Regulation (EC) No 767/2008.

3. Any use of data which does not comply with paragraphs 1 and 2 shall be considered a misuse under the national law of each Member State.

Article 14

Right of access, correction and deletion

1. The right of persons to have access to data relating to them obtained from the VIS pursuant to this Decision shall be exercised in accordance with the law of the Member State in which they invoke that right.

2. If national law so provides, the national supervisory authority shall decide whether information is to be communicated and by what procedures.

3. A Member State other than that which has entered the data into the VIS according to Regulation (EC) No 767/2008 may communicate information concerning such data only if it first gives the Member State entering the data an opportunity to state its position.

4. Information shall not be communicated to the data subject if this is indispensable for the performance of a lawful task in connection with the data or for the protection of the rights and freedoms of third parties.

5. Any person has the right to have factually inaccurate data relating to him corrected or unlawfully stored data relating to him deleted. If the designated authorities receive such a request or if they have any other evidence to suggest that data processed in the VIS is inaccurate they shall immediately inform the visa authority of the Member State which has entered the data in the VIS, which shall check the data concerned and, if necessary, correct or delete it immediately, pursuant to Article 24 of Regulation (EC) No 767/2008.

6. The individual concerned shall be informed as soon as possible and in any event not later than 60 days from the date on which he applies for access or sooner if national law so provides.

7. The individual concerned shall be informed about the follow-up given to the exercise of his rights of correction and deletion as soon as possible and in any event not later than three months from the date on which he applies for correction or deletion or sooner if national law so provides.

8. In each Member State any person shall have the right to bring an action or a complaint before the competent authorities or courts of that Member State which refused the right of access to or the right of correction or deletion of data relating to him, provided for in this Article.

Article 15

Costs

Each Member State and Europol shall set up and maintain, at their expense, the technical infrastructure necessary to implement this Decision, and be responsible for bearing the costs resulting from access to the VIS for the purposes of this Decision.

Article 16

Keeping of records

1. Each Member State and Europol shall ensure that all data processing operations resulting from access to the VIS for consultation pursuant to this Decision are recorded for the purposes of checking whether the search is admissible or not, for the purpose of monitoring the lawfulness of data processing, for self-monitoring, ensuring the proper functioning of the system, data integrity and security.

Those records shall show:

(a) the exact purpose of the access for consultation referred to in Article 5(1)(a), including the form of terrorist offence or other serious criminal offence concerned, and for Europol, the exact purpose of the access for consultation referred to in Article 7(1);

(b) the respective national file reference;

(c) the date and exact time of access;

(d) where applicable that use has been made of the procedure referred to in Article 4(2);

(e) the data used for consultation;

(f) the type of data consulted;

(g) according to national rules or the rules of the Europol Convention the identifying mark of the official who carried out the search and of the official who ordered the search or supply.

2. Records containing personal data shall be used only for the data protection monitoring of the legality of data processing as well as to ensure data security. Only records containing data of a non-personal nature may be used for the monitoring and evaluation referred to in Article 17.

3. These records shall be protected by appropriate measures against unauthorised access and abuse and deleted after a period of one year after the retention period referred to in Article 23(1) of Regulation (EC) No 767/2008 has expired, unless they are required for monitoring procedures referred to in paragraph 2 of this Article which have already begun.

Article 17

Monitoring and evaluation

1. The Management Authority referred to in Regulation (EC) No 767/2008 shall ensure that systems are in place to monitor the functioning of the VIS pursuant to this Decision against objectives, in terms of output, cost-effectiveness, security and quality of service.

2. For the purpose of technical maintenance, the Management Authority shall have access to the necessary information relating to the processing operations performed in the VIS.

3. Two years after the VIS is brought into operation and every two years thereafter, the Management Authority shall submit a report to the European Parliament, the Council and the Commission on the technical functioning of the VIS pursuant to this Decision. That report shall include information on the performance of the VIS against quantitative indicators predefined by the Commission, and in particular on the need and use made of Article 4(2).

4. Three years after the VIS is brought into operation and every four years thereafter, the Commission shall produce an overall evaluation of the VIS pursuant to this Decision. This evaluation shall include an examination of the results achieved against objectives and an assessment of the continuing validity of the underlying rationale behind this Decision, the application of this Decision in respect of the VIS, the security of the VIS and any implications for future operations. The Commission shall transmit the evaluation reports to the European Parliament and the Council.

5. The Member States and Europol shall provide to the Management Authority and the Commission the information necessary to draft the reports referred to in paragraph 3 and 4. This information shall not jeopardise working methods nor include information that reveals sources, staff members or investigations of the designated authorities.

6. The Management Authority shall provide the Commission with the information necessary to produce the overall evaluations referred to in paragraph 4.

7. During the transitional period before the Management Authority takes up its responsibilities, the Commission shall be responsible for producing and submitting the reports referred to in paragraph 3.

Article 18

Entry into force and date of application

1. This Decision shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

2. This Decision shall take effect from a date to be determined by the Council once the Commission has informed the Council that Regulation (EC) No 767/2008 has entered into force and is fully applicable.

The General Secretariat of the Council shall publish that date in the *Official Journal of the European Union*.

Done at Luxembourg, 23 June 2008.

For the Council

The President

I. JARC