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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on Community statistics on public health and health and safety at work

(presented by the Commission)

EXPLANATORY MEMORANDUM

1) CONTEXT OF THE PROPOSAL

- **Grounds for and objectives of the proposal**

This proposal for a Regulation (EC) of the European Parliament and of the Council concerning Community statistics on public health and health and safety at work aims at establishing the framework for the systematic production of statistics in these two areas, in the form of a minimum data set, carried out by the European Statistical System, i.e. Eurostat, the national statistical institutes and all other national authorities responsible for the provision of official statistics in these areas. Consequently, this Regulation is only focused on statistical activities developed under article 285 of the Treaty establishing the European Community. Its aim is not on policy developments for the two areas of public health and health and safety at work, which are carried out respectively under articles 152 and 137 of the Treaty. The production of Community statistics is governed by the rules set out in Council Regulation (EC) No 322/97 of 17 February 1997, as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council.

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 and Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 making it applicable to the Community institutions and bodies allow the processing of personal data on health for reasons of substantial public interest subject to provision of appropriate safeguards. The Community and national political actions and strategies in the areas of public health and health and safety at work constitute a substantial public interest and the provisions of the Council Regulations (EC) No 322/97 and (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 (Eurostat) provide the appropriate safeguards for the protection of individuals in the case of the production of Community statistics on public health and health and safety at work.

- **General context**

The methodological developments for Eurostat statistical activities in both areas of public health and health and safety at work started in the first half of the 90's, with first data collection starting with reference years 1993-1994. The sustainability and quality improvement of these data collections already in place as well as a successful implementation of new statistical data collections for which methodologies have been or are being developed in both areas are clearly needed by the relevant European policies. Actually, the Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health 2003-2008, the Council Resolution No 2002/C 161/01 of 3 June 2002 on a new Community strategy on health and safety at work 2002-2006 and the Commission Communication of 20 April 2004 on "modernising social protection for the development of high-quality, accessible and sustainable health care and long-term care: support for the national strategies using the 'open method of coordination'", require a high standard statistical information system for assessing achievements of policies and developing and monitoring further actions in both areas. This will be continued and developed under successor programmes and strategies.

Until now, statistical data collections were carried out on the basis of "gentlemen agreements" with the Member States in the framework of the five years Community Statistical Programmes (currently Decision 2367/2002/EC of the European Parliament and Council of 16 December 2002 on the Community statistical programme 2003 to 2007) and its annual components. In particular in the area of public health statistics, the developments and implementations in the three strands (causes of deaths, health care and health interview surveys, disability and morbidity) are steered and organised according to a partnership structure between Eurostat, together with leading countries (currently United Kingdom as general coordinator and respective domain leaders from Estonia, Luxembourg and Denmark), and Member States. In this framework, a lot of methodological work, including preparation of guidelines, has been already achieved and the implementation of data collections has started.

However, the current situation is characterised by the following limitations. First, for data collection already implemented, though a certain increase in data quality and comparability has been achieved, Member States should be given a firm basis for implementation. A legal framework would allow a consolidation of the progress towards better quality and comparability standards for all related routine data collections. It will ensure a better sustainability and stability of the European requirements for the medium term and would give clear targets in terms of standards to be achieved for comparability at EU level. Moreover, a high majority of the new Member States stated that, for the implementation of both the full statistical "acquis communautaire" and new statistical collections to be set up in near future, they will not be able to comply with the EU requirements in the areas of public health and health and safety at work statistics without a European legal framework. Finally, all Member States need a clearer view on the time schedule and milestones for the implementation of the new statistical tools, currently being developed, and of the actions being prepared for quality improvement. The proposed regulation will be an appropriate framework for drawing up detailed roadmaps in the various areas and strands of health and safety statistics.

This is why the Commission (Eurostat) considers it is necessary now to give a firm basis through providing a basic legal act in the areas of public health and health and safety at work statistics. The domains covered by the proposal for a European Parliament and Council Regulation relate to ongoing activities and developments carried out together with the Member States in the relevant groups of Eurostat or, in the area of public health, of the Partnership on public health statistics. The main goal is to give a consolidated and firm basis for collections already implemented or which methodology is currently being developed or implementation prepared.

- **Existing provisions in the area of the proposal**

There are no existing provisions in the area of the proposal.

- **Consistency with other policies and objectives of the Union**

The Programme of Community action in the field of public health (2003-2008), stated that the statistical element of the information system on public health will be developed, in collaboration with Member States, using as necessary the Community statistical programme to promote synergy and avoid duplication. The amended proposal for a Decision of the European Parliament and of the Council establishing a second programme of Community action in the field of health 2007-2013 (COM (2006) 234 final), stated that the existing work to develop an EU health monitoring system shall be expanded, using the Community Statistical Programme as necessary. For its part, the Community strategy on health and safety

at work 2002-2006 called on the Commission and the Member States to step up work in hand on harmonisation of statistics on accidents at work and occupational illnesses, so as to have available comparable data from which to make an objective assessment of the impact and effectiveness of the measures taken under the Community strategy.

2) CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

• Consultation of interested parties

Consultation methods, main sectors targeted and general profile of respondents

- Meetings with the Core Groups in charge of steering developments and implementations in each of the three strands of the Partnership on public health statistics - first quarter 2005.
- Meetings with the Eurostat Technical Groups in the area of health and safety at work statistics (one group on accidents at work and another one on occupational diseases) - February and April 2005.
- Written consultation of all Member States in the framework of the two Eurostat public health statistics and health and safety at work statistics Working Groups - May to September 2005.
- Meeting of the Directors of Social Statistics of the National Statistical Institutes on 28-29 September 2005.
- Meeting of the Statistical Programme Committee on 29-30 November 2005.

In addition an information was provided to the following groups:

- Meetings of the Technical Groups in each of the three strands of the Partnership on public health statistics - May to September 2005.
- Meeting of the Network of Competent Authorities of the Health Information strand of the Community action in the field of public health 2003-2008 - 5-6 July 2005.
- Public Health Working Group of the Council - 7 November 2005.
- Tripartite Advisory Committee on Safety and Health at Work - 25 November 2005.
- High Level Committee on Health - 14-15 December 2005.

Summary of responses and how they have been taken into account

In the framework of the Partnership on public health statistics groups, the experts supported the proposal and provided detailed comments for improvements of technical contents which were taken into consideration in the final drafting. In the framework of the other meetings and written consultation of the Eurostat Working Groups, the majority of the Member States also supported the proposal. However, some Member States considered the gentlemen agreement procedure as more flexible for this area, some others required to concentrate on the achievement of a minimum statistical data set in these areas (taken into consideration in the final drafting) and others required to consult the demand side groups (actually an information was provided to various groups including the Council Working Group on Public Health). Finally, Member States required that an impact assessment will be provided at the time of the adoption of the proposal by the Commission; Eurostat is preparing the "analysis of the

consequences" of the proposal. Finally detailed comments from Member States and Commission services were taken into consideration.

- **Collection and use of expertise**

Scientific/expertise domains concerned

For public health: Partnership on Public Health statistics, general coordinator, domain leaders and core groups members.

For health and safety at work: members of the Eurostat Technical Groups of the European Statistics on Accidents at Work (ESAW) and the European Occupational Diseases Statistics (EODS).

Methodology used

Discussion at meetings.

Main organisations/experts consulted

For public health: Office for National statistics of UK, Inspection Générale de la Sécurité Sociale of Luxembourg, Central Statistical Office of Ireland until June 2005 and since then National Statistical Institute of Estonia, National Institute of Public Health of Denmark.

For health and safety at work: members of the respective technical groups (all Member States).

Summary of advice received and used

The existence of potentially serious risks with irreversible consequences has not been mentioned.

They provided support in drafting some articles of the proposal and the detailed contents of the five annexes.

Means used to make the expert advice publicly available

Working documents and minutes of the following meetings, available on the respective Eurostat Circa sites:

- Directors of Social Statistics 28-29/09/2005;

- Eurostat Public Health Statistics Working Group 28-29/11/2005;

- Eurostat Technical Groups in on accidents at work statistics 25/02/2005 and on occupational diseases 26/04/2005 as well as Eurostat Health and Safety at Work Working Group 6-7/10/2005.

- **Impact assessment**

An "Analyses of the consequences" (impact assessment in the case of Community statistics legislation) has been carried out. The three options considered are :

- No action, i.e. continue to develop statistics in the areas of public health and health and safety at work using a "gentlemen agreements" with the Member States in the framework of the five years Community Statistical Programmes;
- The development and adoption of various proposals for Regulations (EC) of the European Parliament and of the Council concerning either public health statistics and health and safety at work separately or each domain and related statistical tool separately;
- The development and adoption of the current proposal for a Regulation (EC) of the European Parliament and of the Council concerning Community statistics on public health and health and safety at work.

3) LEGAL ELEMENTS OF THE PROPOSAL

- **Summary of the proposed action**

The proposal for a Regulation (EC) of the European Parliament and of the Council on public health and health and safety at work statistics aims at establishing the framework for all current and foreseeable activities in the field of Public health and Health and Safety at Work statistics carried out by the European Statistical System. It is proposed to formulate a general Regulation on all domains concerned together. The reason is to have a global and coherent approach to responding to policy needs and to promote synergies as health issues at work and outside workplace, and their different elements, are linked; when relevant, some statistical collections can usefully be carried out for both areas together, using common tools such as population surveys. The proposed regulation sets the general principles and describes the main contents of the related data collections in Annexes I to V for the 5 domains concerned, namely statistics on health status and health determinants, health care, causes of death, accidents at work as well as occupational diseases and other work-related health problems and illnesses. The elements on the statistical methodologies and data collection will be set up by Commission implementing regulations and specified into details in manuals and guidelines.

- **Legal basis**

Article 285 of the Treaty establishing the European Community provides the legal basis for Community statistics. The Council, acting in accordance with the codecision procedure, shall adopt measures for the production of statistics where necessary for the performance of the activities of the Community. This Article sets out requirements relating to the production of Community statistics and requires conformity to standards of impartiality, reliability, objectivity, scientific independence, cost-effectiveness and statistical confidentiality. This Article implies that measures for the production of statistics are of exclusive competence at Community level.

- **Subsidiarity principle**

Since the objectives of the proposed action, namely the production of Community statistics on public health and health and safety at work, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level on the basis of a Community legal act because only the Commission can coordinate the necessary harmonisation of statistical information at Community level, while the collection of data and compilation of comparable statistics on public health and health and safety at work can be organised by the

Member States, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty.

- **Proportionality principle**

The proposal complies with the proportionality principle for the following reason(s).

In the framework of the proposed Regulation, only measures that have an important impact for the implementation and quality of the statistical data collections, such as the definition of variables, breakdowns, dates of implementation and frequency, etc., in priority domains or part of domains to be selected with the Member States, should be included in implementing measures. Main elements on sources may be also included but a high level of flexibility will be let for decisions at national level. Similarly, decisions of a more technical or very detailed nature, as guidelines, detailed classifications, etc., will be decided and included only in methodological manuals in order to allow a flexible and proportionate implementation in the Member States.

For example, in the field of surveys, the future European Health Interview Survey (EHIS) will be carried out every five years at the same time in all Member States. The subjects and breakdowns, for which questions are developed at EU level and are translated into all EU official languages (in order to avoid as much as possible linguistic and cultural biases), will be defined in an implementing regulation. However, Member States will have the choice either to set up a new survey or to include the EHIS questions in the national health or population surveys they consider appropriate.

The Commission (Eurostat) does not aim at adding new general requirements to the agreements already achieved but to support quality, comparability and timeliness improvements.

- **Choice of instruments**

Proposed instruments: regulation

Other means would not be adequate for the following reason(s).

Gentlemen agreement procedures do not allow achieving sufficient comparability, coverage and timeliness. They will not give sufficient priority and resources for the preparation and implementation of statistical data collections on health and safety. In particular financing will not be ensured. This is why a European legal framework is necessary. A Regulation of the European Parliament and Council is the legal instrument most appropriate for statistical actions which require detailed and uniformed application throughout the Community.

4) BUDGETARY IMPLICATION

Main financing of actions for statistics in the areas of public health and health and safety at work will be covered by the Community statistical programme 2003 to 2007 (Decision no 2367/2002/EC of the European Parliament and of the Council) and the future Community statistical programme 2008-2012.

Complementary financing shall be provided from operational resources made available by Directorates General Health and Consumer Protection and Employment and Social Affairs in the framework of the:

- second Programme of Community action in the field of health 2007-2013 (COM (2006) 234 final, amended proposal for a Decision of the European Parliament and of the Council);

- Community programme for employment and social solidarity – PROGRESS (COM (2005) 536 final, amended proposal for a Decision of the European Parliament and of the Council).

5) ADDITIONAL INFORMATION

- **European Economic Area**

The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

- **Detailed explanation of the proposal**

The text follows the standard model act for statistical Regulations of the European Parliament and Council.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on Community statistics on public health and health and safety at work

(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 Commission¹,

Having regard to the opinion of the European Economic and Social Committee²,

After consulting the European Data Protection Supervisor,

After consulting the Statistical Programme Committee (SPC) in accordance with Art. 3(1) of Council Decision No 89/382/EEC, Euratom³,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁴,

Whereas:

- (1) Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) (⁵), stated that the statistical element of the information system on public health is to be developed, in collaboration with Member States, using as necessary the Community statistical programme to promote synergy and avoid duplication.
- (2) Community information on public health has been developed systematically through the Community public-health programmes. Building on this work, a list of European Community Health Indicators (ECHI) has now emerged providing an overview of health status, determinants of health and health systems. In order to make available the minimum statistical data set needed for the calculation of ECHI indicators, Community statistics on health should be consistent, when relevant and possible, with the developments and achievements resulting from Community action in the field of public health.

⁽¹⁾ OJ C , , p. .

⁽²⁾ OJ C , , p. .

⁽³⁾ OJ L 181, 28.06.1989, p. 47.

⁽⁴⁾ OJ C , , p. .

⁽⁵⁾ OJ L 271, 09.10.2002, p. 1.

- (3) Council Resolution No 2002/C 161/01 of 3 June 2002 on a new Community strategy on health and safety at work (2002-2006) ⁽⁶⁾ called on the Commission and the Member States to step up work in hand on harmonisation of statistics on accidents at work and occupational illnesses, so as to have available comparable data from which to make an objective assessment of the impact and effectiveness of the measures taken under the new Community strategy. In addition, Commission Recommendation C(2003) 3297 final of 19 September 2003 concerning the European schedule of occupational diseases recommended that the Member States progressively make their statistics on occupational diseases compatible with the European schedule, in accordance with the work being done on harmonising European statistics on occupational diseases.
- (4) In 2002 the Barcelona European Council recognised three guiding principles for the reform of health care systems: accessibility for all, high quality care and long-term financial sustainability. The Commission Communication ⁽⁷⁾ of 20 April 2004 to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on “modernising social protection for the development of high-quality, accessible and sustainable health care and long-term care: support for the national strategies using the ‘open method of coordination’”, proposed starting work to identify possible indicators for joint objectives to develop care systems on the basis of activities undertaken in the context of the Community action programme on health, of Eurostat health statistics and cooperation with international organisations.
- (5) Decision No 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 laying down the sixth Community Environment Action Programme ⁽⁸⁾ includes an action on environment and health and quality of life as a key priority, calling for the definition and development of indicators of health and environment. In addition, the Council conclusions of 8 December 2003 requested that indicators on biodiversity and health be included, under the title “environment”, in the structural indicators database used for the annual Spring Report to the European Council; health and safety at work indicators are also included in this database, under the title “employment”. The set of sustainable development indicators adopted by the Commission in 2005 also contains a theme on public health indicators.
- (6) The Environment and Health Action Plan 2004-2010 ⁽⁹⁾ recognises the need to improve the quality, comparability and accessibility of data on health status for diseases and disorders linked to the environment, using the Community Statistical Programme.
- (7) Council Resolution No 2003/C 175/01 of 15 July 2003 on promoting the employment and social integration of people with disabilities ⁽¹⁰⁾, called on the Member States and the Commission to collect statistical material on the situation of people with disabilities, including on the development of services and benefits for this group. In addition, the Commission in its Communication of 30 October 2003 to the Council, the European Parliament, the European Economic and Social Committee and the

⁽⁶⁾ OJ C 161, 5.7.2002, p. 1

⁽⁷⁾ COM(2004) 304 final

⁽⁸⁾ OJ L 242, 10.9.2002, p. 1.

⁽⁹⁾ COM(2004) 416 final .

⁽¹⁰⁾ OJ C 175, 24.7.2003, p. 1.

Committee of the Regions on Equal opportunities for people with disabilities - A European action plan ⁽¹¹⁾, decided to develop context indicators which are comparable across Member States in order to assess the effectiveness of disability policies. It indicated that maximum use should be made of sources and structures of the European Statistical System, in particular through development of harmonised survey modules, to acquire the internationally comparable statistical information needed for monitoring progress.

- (8) In order to ensure relevance and comparability of the data and avoid duplication of work, the statistical activities of Eurostat in the area of public health and health and safety at work need to be carried out in cooperation with the United Nations and its special organisations, such as the World Health Organisation (WHO) and the International Labour Organisation (ILO), as well as the Organisation for Economic Cooperation and Development (OECD), when relevant and possible. In particular, a common statistical data collection on the Systems of Health Accounts has been recently implemented together with OECD and WHO.
- (9) The Commission (Eurostat) already collects on a regular basis statistical data on public health and health and safety at work from the Member States which provide such data on a voluntary basis. In addition, it also collects data on those areas through other sources. Those activities are developed in close collaboration with Member States. In the area of public health statistics in particular, development and implementation are steered and organised according to a partnership structure between Eurostat and Member States. However, greater accuracy and reliability, coherence and comparability, coverage, timeliness and punctuality of the existing statistical data collections are still needed and it is also necessary to ensure that further collections agreed and developed with the Member States are implemented in order to achieve the minimum statistical data set necessary at Community level in the areas of public health and health and safety at work.
- (10) The production of specific Community statistics is governed by the rules set out in Council Regulation (EC) No 322/97 of 17 February 1997 on Community Statistics ⁽¹²⁾.
- (11) The present Regulation ensures full respect for the right to the protection of personal data as provided for in Article 8 of the Charter of Fundamental Rights of the European Union.
- (12) Directive No 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 ⁽¹³⁾ 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 ⁽¹⁴⁾ shall apply in the

⁽¹¹⁾ COM(2003) 650 final.

⁽¹²⁾ OJ L 52, 22.2.1997, p. 61. 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).

⁽¹³⁾ 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).

⁽¹⁴⁾ OJ L 8, 12.1.2001, p. 1.

context of this Regulation. The statistical requirements to which Community action in the field of public health, national strategies for the development of high-quality, accessible and sustainable health care and Community strategy on health and safety at work give rise, as well as requirements arising in connection with structural indicators, sustainable development indicators and European Community health indicators and other sets of indicators which it is necessary to develop for the purpose of monitoring Community and national political actions and strategies in the areas of public health and health and safety at work, constitute a substantial public interest.

- (13) The transmission of data subject to statistical confidentiality is governed by the rules set out in Regulation (EC) No 322/97 and in 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⁽¹⁵⁾. Measures which are taken in accordance with those Regulations ensure the physical and logical protection of confidential data and ensure that no unlawful disclosure and non-statistical use occur when Community statistics are produced and disseminated.
- (14) 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, which was adopted by the Statistical Programme Committee on 24 February 2005 and attached to the Commission Communication to the European Parliament and to the Council and promulgated by the Recommendation of the Commission of 25 May 2005 on the independence, integrity and accountability of the national and Community statistical authorities⁽¹⁶⁾.
- (15) Since the objectives of this Regulation, namely the establishment of a common framework for the systematic production of Community statistics on public health and health and safety at work, cannot be sufficiently achieved by the Member States and can therefore 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.
- (16) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision No 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁽¹⁷⁾.
- (17) In particular, the Commission should be empowered to determine definitions, subjects and breakdown (including variables and classifications), sources whenever relevant and provision of data and metadata (including reference periods, intervals and time limits) as regards the domains referred to in Article 2 and in the Annexes 1 to 5 to this Regulation. Since these are measures of general scope designed to amend or delete non-essential elements of this Regulation, or to supplement this Regulation by the addition of new non-essential elements, they should be adopted in accordance with the

⁽¹⁵⁾ OJ L 151, 15.6.1990, p. 1, Regulation as amended by Regulation (EC) No. 322/97.

⁽¹⁶⁾ COM(2005) 217 final and Recommendation of the Commission on the independence, integrity and accountability of the national and Community statistical authorities.

⁽¹⁷⁾ OJ L 184, 17.7.1999, p. 23.

regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EEC.

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

1. This Regulation establishes a common framework for the systematic production of Community statistics on public health and health and safety at work.
2. The statistics shall include, in the form of a minimum data set, information required for Community action in the field of public health, for supporting national strategies for the development of high-quality, accessible and sustainable health care as well as for Community action in the field of health and safety at work.
3. The statistics shall provide data for structural indicators, sustainable development indicators and European Community health indicators as well as for the other sets of indicators which it is necessary to develop for the purpose of monitoring Community actions in the fields of public health and health and safety at work.

Article 2

Scope

Member States shall supply to the Commission (Eurostat) statistics on the following domains:

- health status and health determinants, as defined in Annex I,
- health care, as defined in Annex II,
- causes of death, as defined in Annex III,
- accidents at work, as defined in Annex IV,
- occupational diseases and other work-related health problems and illnesses, as defined in Annex V.

Article 3

Definitions

For the purpose of this Regulation:

- (a) “Community statistics” has the meaning assigned to it by the first indent of Article 2 of Regulation (EC) No 322/97;
- (b) “production of statistics” has the meaning assigned to it by the second indent of Article 2 of Regulation (EC) No 322/97;

(c) “public health” means all elements related to the health of European citizens and residents, namely their health status, including morbidity and disability, the determinants having an effect on that health status, health-care needs, resources allocated to health care, the provision of, and access to, health care as well as the health care expenditure and financing, and the causes of mortality;

(d) “health and safety at work” means all elements related to the prevention and protection of the health and safety of European Union workers at work in their current or past activities, in particular accidents at work, occupational diseases and other work-related health problems and illnesses.

Article 4

Sources

Member States shall compile data concerning public health and health and safety at work from sources which shall consist in, depending on the domains and subjects and on the characteristics of the national systems, either:

- (a) existing or planned household or similar surveys or survey modules, or
- (b) existing or planned national administrative or reporting sources.

Article 5

Methodology, manuals and pilot studies

1. The Commission (Eurostat) shall draw up, or as the case may be improve or update, manuals, guidelines or recommendations on frameworks, concepts and methodologies concerning the Community statistics produced pursuant to this Regulation.

2. National experience and expertise shall be used in the development referred to in paragraph 1. The methods used for the implementation of the data collections shall take into consideration, including in the case of preparatory activities, national specificities, capacities and existing data collections, in the framework of collaborative structures with Member States set up by the Commission (Eurostat). The methodologies for regular data collections which result of projects with a statistical dimension carried out under other Community programmes such as the public health or the research programmes shall also be taken into consideration.

3. The statistical methodologies and data collections to be developed for the compilation of statistics on public health and health and safety at work at Community level shall take into consideration the need for coordination, whenever relevant, with the activities of international organisations in the field, in order to ensure international comparability of statistics and consistency of data collections.

4. Whenever new data requirements or insufficient quality of data are identified in the domains referred to in Article 2, the Commission (Eurostat) shall institute pilot studies to be completed on a voluntary basis by the Member States. The purpose of such pilot studies shall be to test the concepts and methods and to assess the feasibility of the related data collections, including statistical quality, comparability and cost effectiveness, according to the principles

set up by the European Statistics Code of Practice. The approaches used in such studies shall be agreed in the framework of collaborative structures with Member States.

Article 6

Transmission, treatment, dissemination and publication of data

1. Member States shall transmit the microdata or, depending on the domain and subject concerned, the aggregated data, including confidential data as defined by article 13 of Council Regulation (EC) No 322/97, and the metadata, required by this Regulation and measures implementing it, to the Commission (Eurostat) in accordance with the existing Community provisions on transmission of data subject to statistical confidentiality laid down in Council Regulations (EC) No 322/97 and (Euratom, EEC) No 1588/90. Those Community provisions shall apply to the treatment of the data by Eurostat, in so far as the data are considered confidential as defined by article 13 of Council Regulation (EC) No 322/97.

2. Member States shall transmit the data and metadata required by this Regulation in electronic form, in accordance with an interchange standard agreed between the Commission and the Member States. The data shall be provided in accordance with the time-limits set out, at the intervals provided for, and in respect of the reference periods indicated, in the Annexes.

3. The Commission (Eurostat) shall take the necessary steps to improve the dissemination, accessibility and documentation of the statistical information, in accordance with the principles of comparability, reliability and statistical confidentiality laid down in Council Regulation (EC) No 322/97.

Article 7

Quality criteria and reports

1. The Commission (Eurostat) shall assess the quality of the data transmitted.

2. The Commission (Eurostat), in close cooperation with Member States, shall develop recommended common standards designed to ensure the quality and comparability of the data provided, according to the principles set up by the European Statistics Code of Practice. These standards shall be published in the methodological manuals or guidelines.

3. Member States shall take all measures necessary to ensure the best possible quality of the data transmitted.

4. Every five years Member States shall supply the Commission (Eurostat) with two reports, prepared in conformity with the standards referred to in paragraph 2, on the quality of the data transmitted and the sources of the data. The first report shall concern public health statistics and the second health and safety at work statistics. Every five years the Commission (Eurostat) shall draw up a report on the comparability of the data disseminated.

Article 8

Implementing measures

The measures necessary for the implementation of this Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 9(2). The measures shall cover for the domains referred to in Article 2:

- definitions,
- subjects and breakdown, including variables and classifications,
- sources whenever relevant,
- provision of data and metadata, including reference periods, intervals and time limits.

Article 9

Committee

1. The Commission shall be assisted by the Statistical Programme Committee set up by Council Decision 89/382/EEC, Euratom, hereinafter referred to as “the Committee”.

2. Where reference is made to this paragraph, Articles 5a(1) to (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 5(6) of Decision 1999/468/EC shall be three months.

Article 10

This Regulation shall enter into force on the twentieth day following that of 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 Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

Domain: Health status and health determinants

(a) Aims

The aim of this domain is the timely provision of statistics on health status and determinants.

(b) Scope

This domain shall be compiled mainly from population surveys or survey modules on health. Register data or other administrative sources may also be used when providing a complementary coverage and information or for some specific subjects such as morbidity or accidents and injuries. When relevant, persons living in institutions as well as children 0-14 years shall be included, when appropriate subject to successful prior pilot studies.

(c) Reference periods, intervals and time limits of data provision

Statistics shall be provided at least every five years; a more frequent periodicity may be needed for some specific data collections such as on morbidity or accidents and injuries; the first reference year, the interval and the time limit of provision of the data for each source and subject shall be specified and agreed upon as part of the implementing measures referred to in article 8.

(d) Subjects covered

The minimum data set to be provided shall cover the following list of subjects:

- health status, including health perceptions, physical and mental functioning and disability, and morbidity,
- accidents and injuries, including those related to consumer safety,
- lifestyle and environmental, social and occupational factors,
- access and use of preventive and curative health care facilities (population survey),
- background demographic and socio-economic information on the individuals.

Not all subjects are necessarily to be provided at the time of each data provision. The variables, breakdowns and micro data required shall be drawn from the above list.

If survey sources are used, the development of the health survey instruments and the drawing up of recommended characteristics and quality assessment for the survey design, sample and weighting, and realisation shall be carried out according to guidelines drawn up with Member States. These specifications on data collected and surveys used shall be agreed upon in the context of the relevant implementing measures and stated in detail in manuals and guidelines.

(e) Metadata

When submitting the statistical data covered by this domain, the Member States shall provide the required metadata to be agreed upon as part of the implementing measures (including on

survey characteristics) as well as information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators.

ANNEX II

Domain: Health care

(a) Aims

The aim of this domain is the timely provision of statistics on health care.

(b) Scope

This domain covers the sum of activities performed either by institutions or individuals pursuing, through the application of medical, paramedical and nursing knowledge and technology, the goal of health as well as related administration and management activities.

The data shall be compiled mainly from administrative sources.

(c) Reference periods, intervals and time limits of data provision

Statistics shall be provided annually; the first reference year, the interval and the time limit of provision of the data for each source and subject shall be specified and agreed upon as part of the implementing measures referred to in article 8.

(d) Subjects covered

The minimum data set to be provided shall cover the following list of subjects:

- health care institutions and resources,
- health care utilisation, individual and collective services,
- health care expenditures and financing,
- and other elements for supporting national strategies for the development of high-quality, accessible and sustainable health care and long-term care.

Not all subjects are necessarily to be provided at the time of each data provision. The variables and breakdowns required shall be drawn from the above lists. The data set shall be laid down following the International Classification of Health Accounts of the OECD and the International Shortlist for Hospital Morbidity Tabulation of the WHO. These specifications shall be agreed upon in the context of the relevant implementing measures and stated in detail in manuals and guidelines.

(e) Metadata

When submitting the statistical data covered by this domain, the Member States shall provide the required metadata to be agreed upon as part of the implementing measures (including sources, definitions and compilations) as well as information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators.

ANNEX III

Domain: Causes of deaths

a) Aims

The aim of this domain is the timely provision of comparable statistics on the causes of death.

b) Scope

This domain covers the causes of death statistics as derived from national medical death certificates taking into account WHO recommendations. The statistics to be compiled refer to the underlying cause which is defined by WHO as “the disease or injury which initiated the train of morbid events leading directly to death, or the circumstances of the accident or violence which produced the fatal injury”. The statistics shall be compiled for European residents and stillbirths.

c) Reference periods, intervals and time limits of data provision

Statistics shall be provided annually. The first reference year shall be specified and agreed upon as part of the implementing measures referred to in article 8. The data shall be submitted by the latest in the second year following the reference year. Provisional or estimated data can be provided earlier. In the case of public health incidents, special data collections may be additionally established, either for all deaths or for specific causes of death.

d) Subjects covered

The minimum data set to be provided shall cover the following list of subjects:

- characteristics of the deceased,
- region,
- characteristics of the death, including the underlying cause of death.

The variables and breakdowns required shall be drawn from the above list. The causes of death data set shall be laid down in the framework of the International Classification of Diseases of WHO and shall follow the Eurostat rules and the recommendations of UN and WHO for population statistics. These specifications shall be agreed upon in the context of the relevant implementing measures and stated in detail in manuals and guidelines.

e) Metadata

When submitting the statistical data covered by this domain, the Member States shall provide the required metadata to be agreed upon as part of the implementing measures as well as information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators.

ANNEX IV

Domain: Accidents at work

a) Aims

The aim of this domain is the timely provision of statistics on accidents at work.

b) Scope

An accident at work is defined as “a discrete occurrence in the course of work which leads to physical or mental harm”. The data shall be collected, for the entire workforce, for fatal accidents at work and accidents at work resulting in more than 3 days of absence from work, using administrative sources complemented with relevant additional sources. A limited subset of basic data on accidents with less than 4 day’s absence may be collected, when available, in the framework of the collaboration with ILO.

c) Reference periods, intervals and time limits of data provision

Statistics shall be provided annually. The first reference year shall be specified and agreed upon as part of the implementing measures referred to in article 8. The data shall be submitted by the latest in June the second year following the reference year. Provisional data can be submitted earlier.

d) Subjects covered

The minimum micro data set to be provided shall cover the following list of subjects:

- characteristics of the injured person and the injury,
- characteristics of the enterprise and workplace,
- characteristics of the working environment,
- characteristics of the accident, including the sequence of events characterising the causes and circumstances of the accident.

The variables and breakdowns required, as well as their related options and sample weightings, shall be drawn from the above list in the framework of the ESAW methodology. They shall be agreed upon in the context of the relevant implementing measures and stated in detail in manuals and guidelines.

e) Metadata

When submitting the statistical data covered by this domain, the Member states shall provide the required metadata regarding population covered by the statistics, the declaration rates for the accidents at work defined in b) and, when relevant, sample characteristics, as well as information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators.

ANNEX V

Domain: Occupational diseases and other work-related health problems and illnesses

a) Aims

The aim of this domain is the timely provision of statistics on recognised cases of occupational disease and other work-related health problems and illnesses.

b) Scope

A case of occupational disease is defined as a case recognised by the national authorities responsible for recognition of occupational diseases. The data shall be collected for incident occupational diseases and deaths due to occupational disease. A case of work-related health problem and illness does not necessarily refer to recognition by an authority and the related data shall be collected mainly from population surveys.

c) Reference periods, intervals and time limits of data provision

For occupational diseases, statistics shall be provided annually and submitted by the latest in the first quarter of the second year following the reference year. The reference periods, intervals and the time limits of provision of the other data collections shall be specified and agreed upon with Member States.

d) Subjects covered

The minimum data set to be provided shall cover the following list of subjects:

- characteristics of the diseased person and the disease or health-related problems,
- characteristics of the enterprise and workplace,
- characteristics of the causative agent or factor.

Not all subjects are necessarily to be provided at the time of each data provision. The variables and breakdowns required shall be drawn from the above list and agreed upon with Member States.

e) Metadata

When submitting the statistical data covered by this domain, the Member states shall provide the required metadata regarding population covered by the statistics, as well as information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators.