REGULATION (EC) No 1338/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 December 2008

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 Commission,

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

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

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) [3], stated that the statistical element of the information system on public health was to be developed in collaboration with Member States using, as necessary, the Community Statistical Programme to promote synergy and avoid duplication. Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-2013) [4] indicated that its objective of generating and disseminating health information and knowledge would be pursued by actions to develop further a sustainable health monitoring system with mechanisms for collection of comparable data and information, with appropriate indicators, and to develop, with the Community Statistical Programme, the statistical element of this system.

(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, Community statistics on public health should be consistent, when relevant and possible, with the developments and achievements resulting from Community action in the field of public health.

(3) Council Resolution of 3 June 2002 on a new Community strategy on health and safety at work (2002-2006) [5] 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, as well as emphasised, in a specific section, the need to take into account the increase in the proportion of women on the labour market and to respond to their specific needs in relation to policies on health and safety at work. In addition, in its Resolution of 25 June 2007 on a new Community strategy on health and safety at work (2007-2012) [6] the Council called on the Commission to cooperate with the legislative authorities in establishing an appropriate European statistical system in the area of occupational safety and health, which takes account of the different national systems and avoids imposing additional administrative burdens. Finally, in its Recommendation of 19 September 2003 concerning the European schedule of occupational diseases [7], the Commission 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 the system of harmonising European statistics on occupational diseases.

(4) The Barcelona European Council of 15 and 16 March 2002 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 of 20 April 2004 entitled 'Modernising social

[1] OJ C 44, 16.2.2008, p. 103.

[2] Opinion of the European Parliament of 13 November 2007 (OJ C 282 E, 6.11.2008, p. 109), Council Common Position of 2 October 2008 (OJ C 280 E, 4.11.2008, p. 1) and Position of the European Parliament of 19 November 2008 (not yet published in the Official Journal).

[3] OJ L 271, 9.10.2002, p. 1.

[4] OJ L 301, 20.11.2007, p. 3.

[5] OJ C 161, 5.7.2002, p. 1.

[6] OJ C 145, 30.6.2007, p. 1.

[7] OJ L 238, 25.9.2003, p. 28.

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 for developing care systems on the basis of activities undertaken in the context of the Community action programme for health, of Eurostat's health statistics and of cooperation with international organisations. In establishing such indicators, specific attention should be devoted to the use and comparability of self-assessed health as reported in surveys.

(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 ([1]) includes an action on environment and health and quality of life as a key environmental priority, calling for the definition and development of indicators of health and environment. In addition, the Council Conclusions on Structural Indicators 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 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 of 15 July 2003 on promoting the employment and social integration of people with disabilities ([2]) 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 entitled 'Equal opportunities for people with disabilities: A European Action Plan', 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 the Commission (Eurostat) in the area of public health and health and safety at work should 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.

(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. 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 the Commission (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 ([3]).

(11) This 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 ([4]).

(12) 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 ([5]) and Regulation (EC) No 45/2001 of the European Parliament and of the

([1]) OJ L 242, 10.9.2002, p. 1.
([2]) OJ C 175, 24.7.2003, p. 1.
([3]) OJ L 52, 22.2.1997, p. 1.
([4]) OJ C 303, 14.12.2007, p. 1.
([5]) OJ L 281, 23.11.1995, p. 31.

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] apply in the 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 gives rise, as well as requirements arising in connection with structural indicators, sustainable development indicators and ECHI 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 [2]. 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.

(15) Since the objective 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) Recognising that the organisation and management of health care systems are matters of national competence and that the implementation of Community legislation on workplaces and labour conditions is primarily the responsibility of Member States, this Regulation ensures full respect for Member States' competence for public health and health and safety at work.

(17) It is important that gender and age be included in the breakdown variables as this allows the impact of gender and age differences on health and safety at work to be taken into account.

(18) 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].

(19) In particular, the Commission should be empowered to adopt the implementing measures covering characteristics of certain subjects and their breakdown, the reference periods, intervals and time limits for data provision as well as provision of 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.

(20) Complementary financing for the collection of data in the fields of public health and health and safety at work are to be provided respectively within the frameworks of the second programme of Community action in the field of health (2008-13) and of the Community Programme for Employment and Social Solidarity — Progress [4]. Within those frameworks, financial resources should be used to help Member States in further building up national capacities to implement improvements and new tools for statistical data collection in the fields of public health and health and safety at work.

(21) The European Data Protection Supervisor has been consulted.

[1] OJ L 8, 12.1.2001, p. 1.

[2] OJ L 151, 15.6.1990, p. 1.

[3] OJ L 184, 17.7.1999, p. 23.

[4] Decision No 1672/2006/EC of the European Parliament and of the Council of 24 October 2006 establishing a Community Programme for Employment and Social Solidarity — Progress (OJ L 315, 15.11.2006, p. 1).

(22) The Statistical Programme Committee has been consulted in accordance with Article 3(1) of Decision 89/382/EEC, Euratom [1],

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. The statistics shall be produced in compliance with standards on impartiality, reliability, objectivity, cost-effectiveness and statistical confidentiality.

2. The statistics shall include, in the form of a harmonised and common data set, information required for Community action in the field of public health, for supporting national strategies for the development of high-quality, universally 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 (ECHI), 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.

[1] Council Decision 89/382/EEC, Euratom of 19 June 1989 establishing a Committee on the Statistical Programmes of the European Communities (OJ L 181, 28.6.1989, p. 47).

Article 3

Definitions

For the purpose of this Regulation:

(a) 'Community statistics' shall have the meaning assigned to it by the first indent of Article 2 of Regulation (EC) No 322/97;

(b) 'production of statistics' shall have the meaning assigned to it by the second indent of Article 2 of Regulation (EC) No 322/97;

(c) 'public health' shall mean all elements related to health, namely 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 universal access to, health care as well as health care expenditure and financing, and the causes of mortality;

(d) 'health and safety at work' shall mean all elements related to the prevention and protection of the health and safety of workers at work in their current or past activities, in particular accidents at work, occupational diseases and other work-related health problems and illnesses;

(e) 'microdata' shall mean individual statistical records;

(f) 'transmission of confidential data' shall mean transmission between national authorities and the Community authority of confidential data which do not permit direct identification, in accordance with Article 14 of Regulation (EC) No 322/97 and with Regulation (Euratom, EEC) No 1588/90;

(g) 'personal data' shall mean any information relating to an identified or identifiable natural person, in accordance with the Article 2(a) of Directive 95/46/EC.

Article 4

Sources

Member States shall compile data concerning public health and health and safety at work from sources which shall, depending on the domains and subjects and on the characteristics of the national systems, consist of either household or similar surveys or survey modules, or national administrative or reporting sources.

Article 5

Methodology

1. The methods used for the implementation of the data collections shall take into consideration, including in the case of preparatory activities, national experience and expertise, and national specificities, capacities and existing data collections, in the framework of the collaborative networks and other European Statistical System (ESS) structures with Member States set up by the Commission (Eurostat). The methodologies for regular data collections which result from 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.

2. 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, with a view to ensuring international comparability of statistics and consistency of data collections as well as avoiding duplication of effort and of deliveries of data by Member States.

Article 6

Pilot studies and cost-benefit analyses

1. Whenever data are required in addition to those already collected and to those for which methodologies already exist, or when insufficient quality of data is 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, in accordance with the principles set up by the European Statistics Code of Practice.

2. Whenever preparation of an implementing measure is envisaged in accordance with the regulatory procedure with scrutiny referred to in Article 10(2), a cost-benefit analysis, taking into account the benefits of the availability of the data in relation to the cost of the data collection and the burden on Member States, shall be carried out.

3. The Commission (Eurostat) shall prepare a report evaluating the findings of the pilot studies and/or cost benefit analysis, including the effects and implications of national specificities, in cooperation with Member States, in the framework of the collaborative networks and other ESS structures.

Article 7

Transmission, treatment and dissemination of data

1. When necessary for the production of Community statistics, Member States shall transmit the confidential microdata or, depending on the domain and subject concerned, the aggregated data, in accordance with the provisions on transmission of data subject to confidentiality set out in Regulation (EC) No 322/97 and in Regulation (Euratom, EEC) No 1588/90. Those provisions shall apply to the treatment of the data by the Commission (Eurostat), in so far as the data are considered confidential within the meaning of Article 13 of Regulation (EC) No 322/97. Member States shall ensure that the transmitted data do not permit the direct identification of the statistical units (individuals) and that personal data are protected in compliance with the principles laid down in Directive 95/46/EC.

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 (Eurostat) 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 or in the implementing measures adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

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 Regulation (EC) No 322/97 and with Regulation (EC) No 45/2001.

Article 8

Quality assessment

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

(a) 'relevance' shall refer to the degree to which statistics meet the current and potential needs of users;

(b) 'accuracy' shall refer to the closeness of estimates to the unknown true values;

(c) 'timeliness' shall refer to the time lag between the availability of the information and the event or phenomenon it describes;

(d) 'punctuality' shall refer to the time lag between the date of the release of the data and the target date when it should have been delivered;

(e) 'accessibility' and 'clarity' shall refer to the conditions and modalities by which users can obtain, use and interpret data;

(f) '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;

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

2. Every five years each Member State shall provide the Commission (Eurostat) with a report on the quality of the data transmitted. The Commission (Eurostat) shall assess the quality of data transmitted and publish the reports.

Article 9

Implementing measures

1. The implementing measures shall cover:

(a) the characteristics, namely variables, definitions and classifications of the subjects, covered in Annexes I to V;

(b) the breakdown of characteristics;

(c) the reference periods, intervals and time limits for data provision;

(d) the provision of metadata.

These measures shall take account of, in particular, the provisions of Article 5, Article 6(2) and (3) and Article 7(1), as well as the availability, suitability and the legal context of existing Community data sources after examination of all sources related to the respective domains and subjects.

These 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 Article 10(2).

2. If necessary, derogations and transition periods for Member States, both to be based upon objective grounds, shall be adopted in accordance with the regulatory procedure referred to in Article 10(3).

Article 10

Committee

1. The Commission shall be assisted by the Statistical Programme Committee set up by Decision 89/382/EEC, Euratom.

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.

3. 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.

Article 11

Entry into force

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 Strasbourg, 16 December 2008.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
B. LE MAIRE

ANNEX I

Domain: Health status and health determinants

(a) *Aims*

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

(b) *Scope*

This domain covers the statistics on health status and health determinants that are based on self-assessment and compiled from population surveys such as the European Health Interview Survey (EHIS), as well as other statistics compiled from administrative sources such as those on morbidity or accidents and injuries. Persons living in institutions as well as children aged 0-14 years shall be included, when appropriate and at the relevant ad hoc intervals, subject to successful prior pilot studies.

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

Statistics shall be provided every five years from the EHIS; a different frequency may be needed for other data collections, such as those on morbidity or accidents and injuries, as well as for some specific survey modules; the measures relating to the first reference year, the interval and the time limit for provision of the data shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

(d) *Subjects covered*

The harmonised and common data set to be provided shall cover the following list of subjects:

— health status, including health perceptions, physical and mental functioning, limitations and disability,

— diagnosis-specific morbidity,

— protection against possible pandemics and transmissible diseases,

— accidents and injuries, including those related to consumer safety, and, whenever possible, alcohol- and drug-related harm,

— lifestyle, such as physical activity, diet, smoking, alcohol consumption and drug-use, and environmental, social and occupational factors,

— access and use of preventive and curative health care facilities, as well as of long-term care services (population survey),

— background demographic and socio-economic information on the individuals.

Not all subjects are necessarily to be covered at the time of each data provision. The measures relating to the characteristics, namely variables, definitions and classifications of the subjects listed above, and the breakdown of characteristics, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

The implementation of Health Examination Surveys shall be optional in the framework of this Regulation. The average length of the interview per household shall not exceed one hour for the EHIS and 20 minutes for the other survey modules.

(e) *Metadata*

The measures relating to the provision of metadata, including metadata concerning characteristics of surveys and other sources used, population covered and information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

ANNEX II

Domain: Health care

(a) *Aims*

The aim of this domain is the 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, including long-term care, as well as related administration and management activities.

The data shall be compiled mainly from administrative sources.

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

Statistics shall be provided annually. The measures relating to the first reference year, the interval and the time limit for provision of the data shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

(d) *Subjects covered*

The harmonised and common data set to be provided shall cover the following list of subjects:

— health care facilities,

— health care human resources,

— health care utilisation, individual and collective services,

— health care expenditure and financing.

Not all subjects are necessarily to be covered at the time of each data provision. The data set shall be established following the relevant international classifications and taking into consideration the circumstances and practices in Member States.

The mobility of patients, namely their use of health care facilities in a country other than their country of residence, and of health professionals, such as those practising their profession outside the country where they obtained their first licence, shall be considered in the data collections. The quality of health care shall also be considered in the data collection.

The measures relating to the characteristics, namely variables, definitions and classifications of the subjects listed above, and the breakdown of characteristics, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

(e) *Metadata*

The measures relating to the provision of metadata, including metadata concerning characteristics of sources and compilations used, population covered and information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

ANNEX III

Domain: Causes of death

(a) *Aims*

The aim of this domain is the provision of 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 all deaths and stillbirths occurring in each Member State, distinguishing residents and non-residents. Whenever possible, data on causes of death for residents dying abroad shall be included in the statistics of their country of residence.

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

Statistics shall be provided annually. The measures relating to the first reference year shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2). The data shall be submitted no later than 24 months after the end of the reference year. Provisional or estimated data can be provided earlier. In the case of public-health incidents, additional special data collections may be established, either for all deaths or for specific causes of death.

(d) *Subjects covered*

The harmonised and common 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 causes of death data set shall be established in the framework of the WHO International Classification of Diseases and shall follow the Eurostat rules and the UN and WHO recommendations for population statistics. The provision of data relating to the characteristics of stillbirths shall be on a voluntary basis. Provision of data relating to neonatal deaths (deaths up to the age of 28 days) shall recognise national differences in practice regarding the recording of multiple causes of death.

The measures relating to the characteristics, namely variables, definitions and classifications of the subjects listed above, and the breakdown of characteristics, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

(e) *Metadata*

The measures relating to the provision of metadata, including metadata concerning population covered and information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

ANNEX IV

Domain: Accidents at work

(a) *Aims*

The aim of this domain is the 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 three days of absence from work, using administrative sources complemented with relevant additional sources whenever necessary and feasible for specific groups of workers or specific national situations. A limited subset of basic data on accidents with less than four days of absence may be collected, when available and on an optional basis, in the framework of the collaboration with the ILO.

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

Statistics shall be provided annually. The measures relating to the first reference year shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2). The data shall be submitted no later than 18 months after the end of the reference year.

(d) *Subjects covered*

The harmonised and common microdata set to be provided shall cover the following list of subjects:

— characteristics of the injured person,

— characteristics of the injury, including severity (days lost),

— characteristics of the enterprise including economic activity,

— characteristics of the workplace,

— characteristics of the accident, including the sequence of events characterising the causes and circumstances of the accident.

The accidents-at-work data set shall be established in the framework of the specifications laid down by the European Statistics on Accidents at Work (ESAW) methodology, taking into consideration the circumstances and practices in Member States.

The provision of data relating to the nationality of the injured person, the size of the enterprise and the time of the accident shall be on a voluntary basis. Concerning the ESAW-methodology Phase III subjects, namely the workplace and the sequence of events characterising the causes and circumstances of the accident, a minimum of three variables shall be provided. Member States should also supply more data conforming to the ESAW Phase III specifications on a voluntary basis.

The measures relating to the characteristics, namely variables, definitions and classifications of the subjects listed above, and the breakdown of characteristics, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

(e) *Metadata*

The measures relating to the provision of metadata, including metadata concerning population covered, the declaration rates for accidents at work and, when relevant, sampling characteristics, as well as information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

ANNEX V

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

(a) *Aims*

The aim of this domain is the 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.

— Work-related health problems and illnesses are those health problems and illnesses which can be caused, worsened or jointly caused by working conditions. This includes physical and psychosocial health problems. 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 from existing population surveys such as the European Health Interview Survey (EHIS) or other social surveys.

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

For occupational diseases, statistics shall be provided annually and submitted no later than 15 months after the end of the reference year. The measures relating to the reference periods, the intervals and the time limits for provision of the other data collections shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

(d) *Subjects covered*

The harmonised and common data set to be provided for occupational diseases shall cover the following list of subjects:

— characteristics of the diseased person, including gender and age,

— characteristics of the disease, including severity,

— characteristics of the enterprise and workplace, including economic activity,

— characteristics of the causative agent or factor.

The occupational diseases data set shall be established in the framework of the specifications laid down by the European Occupational Diseases Statistics (EODS) methodology, taking into consideration the circumstances and practices in Member States.

The harmonised and common data set to be provided for work-related health problems shall cover the following list of subjects:

— characteristics of the person suffering the health problem, including gender, age and employment status,

— characteristics of the work-related health problem, including severity,

— characteristics of the enterprise and workplace, including size and economic activity,

— characteristics of the agent or factor that caused the health problem or made it worse.

Not all subjects are necessarily to be covered at the time of each data provision.

The measures relating to the characteristics, namely variables, definitions and classifications of the subjects listed above, and the breakdown of characteristics, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).

(e) *Metadata*

The measures relating to the provision of metadata, including metadata concerning population covered and information about any national specificity essential for the interpretation and compilation of comparable statistics and indicators, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 10(2).