►B 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)

(OJ L 354, 31.12.2008, p. 70)

Amended by:

		Official Journal		
		No	page	date
►M1	Regulation (EU) 2019/1700 of the European Parliament and of the Council of 10 October 2019	L 261I	1	14.10.2019

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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.

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;

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(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.

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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.

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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).

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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.

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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.

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(b) *Scope*

This domain covers the statistics on health status and health determinants that are based on self-assessment and compiled from population surveys other than those compiled from data collection with regard to households and individuals referred to in Regulation (EU) 2019/1700 of the European Parliament and of the Council [1], 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 up to the age of 14 shall be included, where appropriate and at relevant ad hoc intervals, subject to successful prior pilot studies.

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

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).

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(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.

[1] Regulation (EU) 2019/1700. of the European Parliament and of the Council of 10 October 2019 establishing a common framework for European statistics relating to persons and households, based on data at individual level collected from samples, amending Regulations (EC) No 808/2004, (EC) No 452/2008 and (EC) No 1338/2008 of the European Parliament and of the Council, and repealing Regulation (EC) No 1177/2003 of the European Parliament and of the Council and Council Regulation (EC) No 577/98 (OJ L 261 I, 14.10.2019, p. 1).

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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).

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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 20 minutes for the survey modules.

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(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).

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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).

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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).

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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).

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(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).

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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,

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— 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).