

Official Journal

of the European Communities

ISSN 0378 - 6978

L 196

Volume 33

26 July 1990

English edition

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II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 28 June 1990

on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)

(90/394/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 118a thereof,

Having regard to the proposal from the Commission ⁽¹⁾, drawn up following consultation with the Advisory Committee on Safety, Hygiene and Health Protection at Work,

In cooperation with the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas Article 118a of the Treaty provides that the Council is to adopt, by means of Directives, minimum requirements in order to encourage improvements, especially in the working environment, so as to guarantee better protection of the health and safety of workers;

Whereas, according to that Article, such directives must avoid imposing administrative, financial and legal constraint in a way which would hold back the creation and development of small and medium-sized undertakings;

Whereas the Council resolution of 27 February 1984 on a second action programme of the European Communities on safety and health at work ⁽⁴⁾ provides for the development of protective measures for workers exposed to carcinogens;

Whereas the Commission communication on its programme concerning safety, hygiene and health at work ⁽⁵⁾ provides for the adoption of Directives to guarantee the health and safety of workers;

Whereas compliance with the minimum requirements designed to guarantee a better standard of health and safety as regards the protection of workers from the risks related to exposure to carcinogens at work is essential to ensure the health and safety of workers;

Whereas this Directive is an individual Directive within the meaning of Article 16 (1) of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the health and safety of workers at work ⁽⁶⁾; whereas therefore the provisions of that Directive are fully applicable to the exposure of workers to carcinogens, without prejudice to more stringent and/or specific provisions contained in this Directive;

Whereas Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ⁽⁷⁾, as last amended by Directive 88/490/EEC ⁽⁸⁾, contains a list of dangerous substances, together with particulars on the classification and labelling procedures in respect of each substance;

Whereas Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and

⁽¹⁾ OJ No C 34, 8. 2. 1988, p. 9.

⁽²⁾ OJ No C 158, 26. 6. 1989, p. 121 and OJ No C 149, 18. 6. 1990.

⁽³⁾ OJ No C 208, 8. 8. 1988, p. 43.

⁽⁴⁾ OJ No C 67, 8. 3. 1984, p. 2.

⁽⁵⁾ OJ No C 28, 3. 2. 1988, p. 1.

⁽⁶⁾ OJ No L 183, 29. 6. 1989, p. 1.

⁽⁷⁾ OJ No 196, 16. 8. 1967, p. 1.

⁽⁸⁾ OJ No L 259, 19. 9. 1988, p. 1.

administrative provisions relating to the classification, packaging and labelling of dangerous preparations ⁽¹⁾, as last amended by Directive 89/178/EEC ⁽²⁾, contains particulars on the classification and labelling procedures in respect of such preparations;

Whereas the plan of action 1987 to 1989 adopted under the 'Europe against cancer' programme provides for support for European studies on the possible cancer risks of certain chemical substances;

Whereas, although current scientific knowledge is not such that a level can be established below which risks to health cease to exist, a reduction in exposure to carcinogens will nonetheless reduce those risks;

Whereas nevertheless, in order to contribute to a reduction in these risks, limit values and other directly related provisions should be established for all those carcinogens for which the available information, including scientific and technical data, make this possible;

Whereas preventive measures must be taken for the protection of the health and safety of workers exposed to carcinogens;

Whereas this Directive lays down particular requirements specific to exposure to carcinogens;

Whereas this Directive constitutes a practical aspect of the realization of the social dimension of the internal market;

Whereas, pursuant to Decision 74/325/EEC ⁽³⁾, as last amended by the 1985 Act of Accession, the Advisory Committee on Safety, Hygiene and Health Protection at Work is to be consulted by the Commission with a view to drawing up proposals in this field,

HAS ADOPTED THIS DIRECTIVE:

SECTION I

GENERAL PROVISIONS

Article 1

Objective

1. This Directive, which is the sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC, has as its aim the protection of workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens at work.

⁽¹⁾ OJ No L 187, 16. 7. 1988, p. 14.

⁽²⁾ OJ No L 64, 8. 3. 1989, p. 18.

⁽³⁾ OJ No L 185, 9. 7. 1974, p. 15.

It lays down particular minimum requirements in this area, including limit values.

2. This Directive shall not apply to workers exposed only to radiation covered by the Treaty establishing the European Atomic Energy Community.

3. Directive 89/391/EEC shall apply fully to the whole area referred to in paragraph 1, without prejudice to more stringent and/or specific provisions contained in this Directive.

Article 2

Definition

For the purposes of this Directive, 'carcinogen' means:

- (a) a substance to which, in Annex I to Directive 67/548/EEC, the risk-phrase R 45 'may cause cancer' is applied;
- (b) a preparation which, under Article 3 (5) (j) of Directive 88/379/EEC, must be labelled as R 45 'may cause cancer';
- (c) a substance, a preparation or a process referred to in Annex I as well as a substance or preparation released by a process referred to in Annex I.

Article 3

Scope — determination and assessment of risks

1. This Directive shall apply to activities in which workers are or are likely to be exposed to carcinogens as a result of their work.

2. In the case of any activity likely to involve a risk of exposure to carcinogens, the nature, degree and duration of workers' exposure must be determined in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken.

The assessment must be renewed regularly and in any event when any change occurs in the conditions which may affect workers' exposure to carcinogens.

The employer must supply the authorities responsible at their request with the information used for making the assessment.

3. Furthermore, when assessing the risk, account shall be taken of all other cases of major exposure, such as those with harmful effects on the skin.

4. When the assessment referred to in paragraph 2 is carried out, employers shall give particular attention to any effects concerning the health or safety of workers at

particular risk and shall, *inter alia*, take account of the desirability of not employing such workers in areas where they may come into contact with carcinogens.

SECTION II

EMPLOYERS' OBLIGATIONS

Article 4

Reduction and replacement

1. The employer shall reduce the use of a carcinogen at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to workers' health or safety, as the case may be.

2. The employer shall, upon request, submit the findings of his investigations to the relevant authorities.

Article 5

Prevention and reduction of exposure

1. Where the results of the assessment referred to in Article 3 (2) reveal a risk to workers' health or safety, workers' exposure must be prevented.

2. Where it is not technically possible to replace the carcinogen by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to health or safety, the employer shall ensure that the carcinogen is, in so far as is technically possible, manufactured and used in a closed system.

3. Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers is reduced to as low a level as is technically possible.

4. Wherever a carcinogen is used, the employer shall apply all the following measures:

- (a) limitation of the quantities of a carcinogen at the place of work;
- (b) keeping as low as possible the number of workers exposed or likely to be exposed;
- (c) design of work processes and engineering control measures so as to avoid or minimize the release of carcinogens into the place of work;

(d) evacuation of carcinogens at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;

(e) use of existing appropriate procedures for the measurement of carcinogens, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;

(f) application of suitable working procedures and methods;

(g) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures;

(h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces;

(i) information for workers;

(j) demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens;

(k) drawing up plans to deal with emergencies likely to result in abnormally high exposure;

(l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers;

(m) means for safe collection, storage and disposal of waste by workers, including the use of sealed and clearly and visibly labelled containers.

Article 6

Information for the competent authority

Where the results of the assessment referred to in Article 3 (2) reveal a risk to workers' health or safety, employers shall, when requested, make available to the competent authority appropriate information on:

- (a) the activities and/or industrial processes carried out, including the reasons for which carcinogens are used;
- (b) the quantities of substances or preparations manufactured or used which contain carcinogens;
- (c) the number of workers exposed;
- (d) the preventive measures taken;
- (e) the type of protective equipment used;
- (f) the nature and degree of exposure;
- (g) the cases of replacement.

*Article 7***Unforeseen exposure**

1. In the event of an unforeseeable event or an accident which is likely to result in an abnormal exposure of workers, the employer shall inform the workers thereof.
2. Until the situation has been restored to normal and the causes of the abnormal exposure have been eliminated:
 - (a) only those workers who are essential to the carrying out of repairs and other necessary work shall be permitted to work in the affected area;
 - (b) the workers concerned shall be provided with protective clothing and individual respiratory protection equipment which they must wear; the exposure may not be permanent and shall be kept to the strict minimum of time necessary for each worker;
 - (c) unprotected workers shall not be allowed to work in the affected area.

*Article 8***Foreseeable exposure**

1. For certain activities such as maintenance, in respect of which it is foreseeable that there is the potential for a significant increase in exposure of workers, and in respect of which all scope for further technical preventive measures for limiting workers' exposure has already been exhausted, the employer shall determine, after consultation of the workers and/or their representatives in the undertaking or establishment, without prejudice to the employer's responsibility, the measures necessary to reduce the duration of workers' exposure to the minimum possible and to ensure protection of workers while they are engaged in such activities.

Pursuant to the first subparagraph, the workers concerned shall be provided with protective clothing and individual respiratory protection equipment which they must wear as long as the abnormal exposure persists; that exposure may not be permanent and shall be kept to the strict minimum of time necessary for each worker.

2. Appropriate measures shall be taken to ensure that the areas in which the activities referred to in the first subparagraph of paragraph 1 take place are clearly demarcated and indicated or that unauthorized persons are prevented by other means from having access to such areas.

*Article 9***Access to risk areas**

Appropriate measures shall be taken by employers to ensure that access to areas in which the activities in respect of which the results of the assessment referred to in Article 3 (2) reveal

a risk to workers' safety or health take place are accessible solely to workers who, by reason of their work or duties, are required to enter them.

*Article 10***Hygiene and individual protection**

1. Employers shall be obliged, in the case of all activities for which there is a risk of contamination by carcinogens, to take appropriate measures to ensure that:
 - (a) workers do not eat, drink or smoke in working areas where there is a risk of contamination by carcinogens;
 - (b) workers are provided with appropriate protective clothing or other appropriate special clothing;
separate storage places are provided for working or protective clothing and for street clothes;
 - (c) workers are provided with appropriate and adequate washing and toilet facilities;
 - (d) protective equipment is properly stored in a well-defined place;
it is checked and cleaned if possible before, and in any case after, each use;
defective equipment is repaired or replaced before further use.
2. Workers may not be charged for the cost of these measures.

*Article 11***Information and training of workers**

1. Appropriate measures shall be taken by the employer to ensure that workers and/or workers' representatives in the undertaking or establishment receive sufficient and appropriate training, on the basis of all available information, in particular in the form of information and instructions, concerning:
 - (a) potential risks to health, including the additional risks due to tobacco consumption;
 - (b) precautions to be taken to prevent exposure;
 - (c) hygiene requirements;
 - (d) wearing and use of protective equipment and clothing;
 - (e) steps to be taken by workers, including rescue workers, in the case of incidents and to prevent incidents.

The training shall be:

- adapted to take account of new or changed risk, and
- repeated periodically if necessary.

2. Employers shall inform workers of installations and related containers containing carcinogens, ensure that all containers, packages and installations containing carcinogens are labelled clearly and legibly, and display clearly visible warning and hazard signs.

Article 12

Information for workers

Appropriate measures shall be taken to ensure that:

- (a) workers and/or any workers' representatives in the undertaking or establishment can check that this Directive is applied or can be involved in its application, in particular with regard to:
 - (i) the consequences for workers' safety and health of the selection, wearing and use of protective clothing and equipment, without prejudice to the employer's responsibility for determining the effectiveness of protective clothing and equipment;
 - (ii) the measures determined by the employer which are referred to in the first subparagraph of Article 8 (1), without prejudice to the employer's responsibility for determining such measures;
- (b) workers and/or any workers' representatives in the undertaking or establishment are informed as quickly as possible of abnormal exposures, including those referred to in Article 8, of the causes thereof and of the measures taken or to be taken to rectify the situation;
- (c) the employer keeps an up-to-date list of the workers engaged in the activities in respect of which the results of the assessment referred to in Article 3 (2) reveal a risk to workers' health or safety, indicating, if the information is available, the exposure to which they have been subjected;
- (d) the doctor and/or the competent authority as well as all other persons who have responsibility for health and safety at work have access to the list referred to in subparagraph (c);
- (e) each worker has access to the information on the list which relates to him personally;
- (f) workers and/or any workers' representatives in the undertaking or establishment have access to anonymous collective information.

Article 13

Consultation and participation of workers

Consultation and participation of workers and/or their representatives in connection with matters covered by this Directive, including the Annexes hereto, shall take place in accordance with Article 11 of Directive 89/391/EEC.

SECTION III

MISCELLANEOUS PROVISIONS

Article 14

Health surveillance

1. The Member States shall establish, in accordance with national laws and/or practice, arrangements for carrying out relevant health surveillance of workers for whom the results of the assessment referred to in Article 3 (2) reveal a risk to health or safety.

2. The arrangements referred to in paragraph 1 shall be such that each worker shall be able to undergo, if appropriate, relevant health surveillance:

- prior to exposure,
- at regular intervals thereafter.

Those arrangements shall be such that it is directly possible to implement individual and occupational hygiene measures.

3. If a worker is found to be suffering from an abnormality which is suspected to be the result of exposure to carcinogens, the doctor or authority responsible for the health surveillance of workers may require other workers who have been similarly exposed to undergo health surveillance.

In that event, a reassessment of the risk of exposure shall be carried out in accordance with Article 3 (2).

4. In cases where health surveillance is carried out, an individual medical record shall be kept and the doctor or authority responsible for health surveillance shall propose any protective or preventive measures to be taken in respect of any individual workers.

5. Information and advice must be given to workers regarding any health surveillance which they may undergo following the end of exposure.

6. In accordance with national laws and/or practice:

- workers shall have access to the results of the health surveillance which concern them, and
- the workers concerned or the employer may request a review of the results of the health surveillance.

7. Practical recommendations for the health surveillance of workers are given in Annex II.

8. All cases of cancer identified in accordance with national laws and/or practice as resulting from occupational exposure to a carcinogen shall be notified to the competent authority.

Article 15

Record-keeping

1. The list referred to in Article 12 (c) and the medical record referred to in Article 14 (4) shall be kept for at least 40 years following the end of exposure, in accordance with national laws and/or practice.

2. Those documents shall be made available to the responsible authority in cases where the undertaking ceases activity, in accordance with national laws and/or practice.

Article 16

Limit values

1. The Council shall, in accordance with the procedure laid down in Article 118a of the Treaty, set out limit values in Directives on the basis of the available information, including scientific and technical data, in respect of all those carcinogens for which this is possible, and, where necessary, other directly related provisions.

2. Limit values and other directly related provisions shall be set out in Annex III.

Article 17

Annexes

1. Annexes I and III may be amended in accordance only with the procedure laid down in Article 118a of the Treaty.

2. Purely technical adjustments to Annex II in the light of technical progress, changes in international regulations or

specifications and new findings in the field of carcinogens shall be adopted in accordance with the procedure laid down in Article 17 of Directive 89/391/EEC.

Article 18

Use of data

The Commission shall have access to the use made by the competent national authorities of the information referred to in Article 14 (8).

Article 19

Final provisions

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 1992.

Should Directives 67/548/EEC or 88/379/EEC be amended by amending Directives after notification of this Directive with respect to the substances and preparations referred to in Article 2 (a) and (b), Member States shall bring into force the laws, regulations and administrative provisions necessary to introduce the amendments in question into the provisions referred to in the first subparagraph by the deadlines laid down for implementation of such amending Directives.

Member States shall forthwith inform the Commission that the provisions referred to in this paragraph have been brought into force.

2. Member States shall communicate to the Commission the provisions of national law already adopted or which they adopt in the future in the field governed by this Directive.

Article 20

This Directive is addressed to the Member States.

Done at Luxembourg, 28 June 1990.

For the Council

The President

M. GEOGHEGAN-QUINN

ANNEX I**List of substances, preparations and processes***(Article 2 (c))*

1. Manufacture of auramine.
 2. Work involving exposure to aromatic polycyclic hydrocarbons present in coal soots, tar, pitch, fumes or dust.
 3. Work involving exposure to dusts, fumes and sprays produced during the roasting and electro-refining of cupro-nickel mattes.
 4. Strong acid process in the manufacture of isopropyl alcohol.
-

ANNEX II**Practical recommendations for the health surveillance of workers***(Article 14 (7))*

1. The doctor and/or authority responsible for the health monitoring of workers exposed to carcinogens must be familiar with the exposure conditions or circumstances of each worker.
2. Health monitoring of workers must be carried out in accordance with the principles and practices of occupational medicine; it must include at least the following measures:
 - keeping records of a worker's medical and occupational history,
 - a personal interview,
 - where appropriate, biological monitoring, as well as detection of early and reversible effects.

Further tests may be decided upon for each worker when he is the subject of health monitoring, in the light of the most recent knowledge available to occupational medicine.

ANNEX III**Limit values and other directly related provisions***(Article 16)*

- A. Limit values
p.m.
 - B. Other directly related provisions
p.m.
-

COUNCIL DECISION

of 29 June 1990

adopting a specific research and technological development programme in the field of health:
human genome analysis (1990 to 1991)

(90/395/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 130q (2) thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

In cooperation with the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas Article 130k of the Treaty provides that the framework programme is to be implemented through specific programmes developed within each activity;

Whereas, by its Decision 87/516/Euratom, EEC ⁽⁴⁾, as amended by Decision 88/193/EEC, Euratom ⁽⁵⁾, the Council adopted a framework programme for Community activities in the field of research and technological development (1987 to 1991), which defined activities to be undertaken in the field of health;

Whereas that Decision provides that Community action is justified where research contributes, *inter alia*, to the strengthening of the economic and social cohesion of the Community and to the promotion of its overall harmonious development, while being consistent with the pursuit of scientific and technical excellence;

Whereas two successive pluriannual programmes of research and training of the European Economic Community in the field of biotechnologies ⁽⁶⁾, the second of which is still in progress, have shown the possibility and usefulness of Community action promoting the utilization of modern biology for scientific, medical and industrial purposes;

Whereas the framework programme provides, under the heading 'Health' in the 'Quality of Life' section, for the

initiation of new activities relating to the development of knowledge of the human genome;

Whereas, following the adoption of a third Community Framework Programme for activities in the field of research and technological development (1990 to 1994), it is necessary to continue the implementation of the second Framework Programme (1987 to 1991) by means of specific programmes for which the latter makes provision;

Whereas a specific programme to study the human genome is therefore necessary and, in particular, it is necessary to:

- develop and disseminate the basic technologies concerning the study of the human genome, with the intention of improving knowledge of matters of medical importance,
- increase the resolution of the human genetic map and improve the physical map by the creation of ordered clone libraries, as a basis for locating genes of medical importance on chromosomes and for a better general understanding of gene function, and
- organize networks and coordination, on a European and international scale, of researchers from all disciplines working in this field;

Whereas achievement of the abovementioned goals requires the undertaking at Community level of action aimed at:

- filling some existing gaps in scientific and technological knowledge, and
- encouraging cooperation between European research establishments with a view to furthering the development of existing technologies, while promoting all research sectors capable of generating new lines of research;

Whereas, simultaneously, measures must be taken to promote cooperation between the Community programme and similar ones developed in third countries or by international organizations;

Whereas the right to a genetic identity forms part of the integrity and the dignity of an individual and this principle is recognized in the constitutions and laws of Member States and in the Community legal system as forming part of the fundamental rights for which respect is ensured;

Whereas the results which can be achieved from human genome research require the development of an integrated

⁽¹⁾ OJ No C 27, 2. 2. 1989, p. 6 and OJ No C 303, 2. 12. 1989, p. 18.

⁽²⁾ OJ No C 69, 20. 3. 1989, p. 85 and OJ No C 149, 18. 6. 1990.

⁽³⁾ OJ No C 56, 6. 3. 1989, p. 7.

⁽⁴⁾ OJ No L 302, 24. 10. 1987, p. 1.

⁽⁵⁾ OJ No L 89, 6. 4. 1988, p. 35.

⁽⁶⁾ OJ No L 375, 30. 12. 1981, p. 1 and OJ No L 83, 25. 3. 1985, p. 1.

approach, taking into account the medical, ethical, social and legal aspects of the possible applications of such results and the need to avoid any improper use thereof;

Whereas the development of an integrated approach was proposed by the European Parliament in its resolution of 16 March 1989 ⁽¹⁾;

Whereas there are good grounds for guaranteeing the right of an individual to have an informed choice as to whether or not he should receive information concerning his genetic characteristics;

Whereas, in the absence of clear standards and provisions concerning possible developments in the field of genome analysis, there may be a risk, on the one hand, that attempts will be made to intervene in the human genome in order to make the modifications so obtained hereditary and, on the other, that genetic analyses will be carried out for monitoring purposes, which may have a profound effect on social life; whereas there are, accordingly, good grounds for taking the necessary steps to preclude unacceptable developments, particularly in terms of predictive medicine;

Whereas, furthermore, it is necessary to examine in detail, during the course of the programme, the prenormative aspects arising from human genome analysis by establishing a reliable scientific data set which could provide a basis for political authorities to establish sound, clear and responsible rules;

Whereas the Scientific and Technical Research Committee (Crest) has been consulted,

HAS ADOPTED THIS DECISION:

Article 1

A specific research and technological development programme for the European Economic Community in the field of human genome analysis, as defined in Annex II, is hereby adopted for a period of two years commencing on 29 June 1990.

Article 2

1. The funds estimated as necessary for the execution of the programme amount to ECU 14 million, including expenditure on a staff of two.

2. An indicative allocation of funds is set out in Annex I.

⁽¹⁾ OJ No C 96, 17. 5. 1989, p. 165.

Article 3

Detailed rules for the implementation of the programme and the rates of the Community's financial participation are set out in Annex II.

Article 4

1. The Commission shall send the European Parliament and the Council an annual report on the progress of the programme.

2. In the second year of implementation of the programme, the Commission shall review it and send the results of its review to the European Parliament and the Council; the report shall be accompanied, where necessary, by proposals for amendment or extension of the programme.

3. An evaluation of the results achieved shall be carried out by independent experts and published in the form of a communication to the European Parliament and the Council.

4. The abovementioned reports shall be established having regard to the objectives and evaluation criteria set out in Annex II and in accordance with Article 2 (2) of Decision 87/516/Euratom, EEC.

Article 5

The Commission shall be responsible for the execution of the programme. It shall be assisted by a committee of an advisory nature, hereinafter referred to as 'the Committee', composed of the representatives of the Member States and chaired by the representative of the Commission.

Article 6

1. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

2. The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

3. The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

Article 7

The procedure laid down in Article 6 shall apply in particular to:

— the contents of the calls for proposals,

- the assessment of the proposed projects and the estimated amount of the Community's contribution to them,
- departures from the general rules governing Community participation set out in Annex II,
- the participation in any project by third-country organizations and enterprises referred to in Article 8 (2),
- any adjustment to the indicative allocation of resources set out in Annex I,
- the measures to be undertaken to evaluate the programme,
- the arrangements for the dissemination, protection and exploitation of the results of research carried out under the programme.

Article 8

1. The Commission is authorized, in accordance with Article 130n of the Treaty, to negotiate agreements with third countries and international organizations, particularly with third countries participating in European Cooperation in the field of Scientific and Technical Research (COST) and with States which have concluded framework agreements for

scientific and technical cooperation with the Community, with a view to associating them with the programme.

2. Where framework agreements for scientific and technical cooperation between third countries and the European Communities have been concluded, organizations and enterprises established in those countries may, on the basis of the criterion of mutual benefit, become partners in a project undertaken within this programme.

3. No contracting party based outside the Community and participating as a partner in a project undertaken under the programme may benefit from Community financing for this programme. Such contracting party shall contribute to the general administrative costs.

Article 9

This Decision is addressed to the Member States.

Done at Luxembourg, 29 June 1990.

For the Council

The President

M. SMITH

ANNEX I

INDICATIVE INTERNAL ALLOCATION OF RESOURCES

	<i>ECU million</i>
Improvement of the human genetic map	3,3
Physical mapping (ordered clone libraries)	3,4
Data processing and databases	2,2
Improvement of the methods and basis for the study of the human genome	2,2
Training	1,9
Ethical, social and legal aspects	1,0
Management and staff	1,0
TOTAL	15,0

ANNEX II

SPECIFIC RESEARCH PROGRAMME IN THE FIELD OF HEALTH: HUMAN GENOME ANALYSIS

1. OBJECTIVES

Use and improvement of new biotechnologies in the study of the human genome for a better understanding of the mechanisms of genetic functions, as well as the prevention and treatment of human diseases. In the pursuit of these objectives, optimal cooperation will be sought with the programmes of third States and international organizations.

At the same time, measures will be taken to draw up an integrated approach to the medical, ethical, social and legal aspects of possible applications of results obtained through the programme to ensure that they are not misused and also, with pren normative aspects in mind, to establish a set of bioethical principles to be followed in the developments to come.

Alteration of germ cells or any stage of embryo development with the aim of modifying human genetic characteristics in a hereditary manner is excluded from the programme objectives.

2. TECHNICAL CONTENT

Precompetitive Community research, setting up and reinforcement of networks of European laboratories, and training, intended to allow the use of modern technologies for the study and setting up of the human genetic map as well as possible medical applications of the knowledge gained.

The research described below will require the use of data-processing facilities for the handling of data and the setting up of integrated databases to serve European networks, in close cooperation with other Community research programmes.

2.1. Improvement of the human genetic map

Setting up a European network, extending worldwide, for the collection and mapping of the DNA of large families, in order to provide research scientists with well-characterized genetic material and sets of probes to determine the location of the relative positions of genes on the chromosomes.

2.2. Setting up of ordered clone libraries of human DNA

Setting up of a European network of laboratories working on establishing overlapping clone libraries and support for limited sequencing of cDNA.

2.3. Improvement of the methods and basis for the study of the human genome

New biochemical reagents (restriction enzymes, etc.). Improvement of methods for the detection and localization of genetic markers (techniques for labelling DNA probes, amplification of genes, etc.). Development of new vectors for the cloning of large DNA fragments and of procedures for the transfection of chromosomes.

Development of model systems for the reproducible and stable expression of medically important genes both *in vivo* and *in vitro*, aimed at the wellbeing of patients. Development of new computer software for the storage and manipulation of data from genome sequencing and mapping.

2.4. Training

Setting up of a training programme to assist with the technology transfer of molecular genetics methods, in particular to Member States in which these techniques are currently underdeveloped.

3. IMPLEMENTATION

3.1. The programme shall be implemented through entering into cost-shared or marginal cost contracts, support to centralized facilities and new or existing networks, entering into training contracts, issue of training grants, organization of courses, consultations with national experts, organization of

study-group meetings, participation in seminars and symposia, publications, studies, dissemination of results to all interested groups and organization of public presentations.

For shared-cost contracts, the Community participation will be up to 50 % of the total expenditure. However, in the case of universities and research institutes carrying out projects under this programme, the Community may bear up to 100 % of the additional expenditure involved. In other cases, Community participation could reach 100 %.

Participants may be research establishments, universities, private enterprises or combinations thereof located in Member States or in the third countries referred to in Article 8, or competent organizations in a position to make a significant contribution.

Projects must be carried out by participants from more than one country, and include at least two independent partners from two Member States.

Fellows coming from third countries will be accepted in the training programme, provided that they meet the required conditions and that their costs are covered from other sources, such as other Community programmes or actions which support fellows coming from developing countries.

The contracts concluded by the Commission will govern the rights and the obligations of each party, in particular the means of distribution, protection and exploitation of the results of the research.

- 3.2. The drawing up of research contracts can only take place if the contracting parties undertake to abstain in this programme from all research modifying, or seeking to modify, the genetic constitution of human beings by alteration of germ cells or of any stage of embryo development which may make these alterations hereditary.

The contracts shall regulate the granting of licences arising out of research projects and, in particular, there shall be no right to exploit on an exclusive basis any property rights in respect of human DNA. In addition, the Commission shall reserve the right to publish the results of the research performed within the scope of the contracts.

The contracts will guarantee that the members of the families participating in the studies referred to in paragraph 2.1 will be fully informed of, and have consented to the use and study of, their DNA. The contracts will also guarantee complete protection of the confidentiality and anonymity of the personal data obtained in the programme.

- 3.3. The Commission will ensure that during the execution of the programme there will be wide-ranging and in-depth discussion of the ethical, social and legal aspects of human genome analysis and that possible misuses will be identified regarding applications of the results obtained or of future developments of that research. It will ensure that the far-reaching consequences of the research will be evaluated in a responsible manner and will submit to the European Parliament, the Council and the Economic and Social Committee an annual report, possibly with legislative recommendations arising as much from the research policy angle as from the legal one. To this end, the Commission will obtain advice from experts in different fields of science, law, philosophy and ethics, together with representatives of patient's associations.

4. EVALUATION CRITERIA

The communication from the Commission to the Council on a Community action plan relating to the evaluation of Community research and development programmes ⁽¹⁾ states that the objectives and milestones for each research programme have to be set out in verifiable and, where possible, quantitative form. These reference marks are listed below:

- 4.1. The long-term objective of this programme is to contribute to a better understanding of the mechanisms of genetic function as well as to the fight against human diseases arising from genetic variation (including genetic diseases *sensu stricto* and many common diseases with a genetic component, such as heart disease and cancer), through early diagnosis, prevention, and improvement of prognosis and therapy. The Commission proposes to achieve this objective by:

— the organization of networks of laboratories around European facilities for (a) the improvement of the human genetic map, and (b) the setting up of ordered clone libraries of human DNA, either of the complete genome or of selected chromosomes, together with cDNA sequencing,

⁽¹⁾ OJ No C 14, 20. 1. 1987, p. 5.

- the launching of a programme of prenormative research aiming at improvement of the methods and basis of the study of the human genome,
- the setting up of a programme of training to increase the distribution of modern genetic technologies in Europe and to improve technological know-how in European laboratories,
- the promotion of cooperation with third countries and international organizations.

4.2. The primary short-term objective is that the programme should succeed in establishing the abovementioned European networks of laboratories in the fields of:

- the human genetic map,
- ordered clone libraries of human DNA and cDNA sequencing,
- improvement of the methods and basis for the study of the human genome,

by using data-processing facilities for data-handling and by setting up integrated databases.

These objectives should be verifiable in 1991.

4.3. Particular objectives to be attained within two years of the programme's implementation are as follows:

1. Concerning the human genetic map:

- the present total of 40 well-studied large families which form the basis for the genetic map should be increased to 60 families,
- genetic material from these families, and DNA probes, should be made available to the European laboratories concerned, while respecting the individual rights of those families,
- a central facility should be identified to pool the results and establish an improved genetic map at the one to five centimorgan level, and an integrated databank should be set up.

2. The strategies for setting up ordered clone libraries of human DNA should be compared and a better approach defined; facilities for maintaining the stocks of cloned DNA fragments should be established and the available clones dispatched to interested European laboratories.

3. Substantial improvements should be obtained in the following research fields to improve the methods and the basis for the study of the human genome:

- new reagents, such as restriction enzymes,
- methodology for cloning large DNA fragments and for the transfection of chromosomes,
- gene vectors adapted to human somatic cells *in vitro*,
- methodology for the detection of a particular gene in a cell,
- localization, cloning and sequencing of new genes, especially those which are disease-related,
- new computer software for processing of DNA sequence data.

4.4. In addition, the programme should ensure that the following general criteria are met:

1. That throughout the execution of the programme, the ethical, social and legal aspects of human genome analysis should be the subject of wide-ranging and in-depth discussions, and possible abuses of the results or later developments of the work should be identified; principles for their utilization and control should be proposed.
2. That the drawing up of research contracts should presuppose that the contracting parties undertake to abstain in this programme from all research modifying or seeking to modify the genetic constitution of human beings by alteration of germ cells or of any stage of embryo development which may make these alterations hereditary.
3. That the members of the families taking part in the studies mentioned in point 2.1 must have been informed and must have given their consent, and the confidentiality and anonymity of personal data must be ensured.

4. That the development and the application of somatic gene therapy are not provided for within the framework of the present programme.
 5. That only somatic actual or potential medical applications should be facilitated.
 6. That potential opportunities for industrial development should be explored.
 7. That the overall scientific standard of the participating European laboratories must have been improved.
 8. That, taking account of the results of Community, national or commercial research activities in human genetics, the evaluation panel should consider whether the human genome analysis has contributed to the transfer of knowledge and the development of the results of the said activities in regions of the Community other than those in which the research was conducted. The evaluation panel should also ascertain whether cooperation with third countries and international organizations has indeed been achieved and whether this cooperation has had positive results.
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COUNCIL DIRECTIVE

of 29 June 1990

on the approximation of the laws of the Member States relating to appliances burning gaseous fuels

(90/396/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

In cooperation with the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas Member States are responsible for ensuring the health and safety on their territory of their people and, where appropriate, of domestic animals and goods in relation to the hazards arising out of the use of appliances burning gaseous fuels;

Whereas, in certain Member States, mandatory provisions define in particular the safety level required of appliances burning gaseous fuels by specifying design, operating characteristics and inspection procedures; whereas these mandatory provisions do not necessarily lead to different safety levels from one Member State to another but do, by their disparity, hinder trade within the Community;

Whereas different conditions as regards types of gas and supply pressures are in force in the Member States; whereas these conditions are not harmonized because each Member State's energy supply and distribution situation is peculiar to it;

Whereas paragraphs 65 and 68 of the White Paper on the completion of the internal market, approved by the European Council in June 1985, provide for a new approach to legislative harmonization;

Whereas Community law provides — by way of derogation from one of the fundamental rules of the Community, namely the free movement of goods — that obstacles to movement within the Community resulting from disparities in national legislation relating to the marketing of products must be accepted in so far as such obstacles can be recognized as being necessary to satisfy mandatory requirements; whereas, therefore, the harmonization of legislation in the

present case must be limited to the provisions necessary to satisfy both the mandatory and essential requirements regarding safety, health and energy conservation in relation to gas appliances; whereas these requirements must replace the national provisions in this matter because they are essential requirements;

Whereas the maintenance or improvement of the level of safety attained in Member States constitutes one of the essential aims of this Directive and of safety as defined by the essential requirements;

Whereas the essential safety and health requirements must be observed in order to ensure that appliances burning gaseous fuels are safe; whereas energy conservation is considered essential; whereas these requirements must be applied with discernment to take account of the state of the art at the time of construction;

Whereas this Directive therefore contains only essential requirements; whereas, to facilitate proof of conformity with the essential requirements, it is necessary to have harmonized standards at European level in particular as to the construction, operation and installation of appliances burning gaseous fuels so that products complying with them may be assumed to conform to the essential requirements; whereas these standards, harmonized at European level, are drawn up by private bodies and must remain non-mandatory texts; whereas for that purpose the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are recognized as the competent bodies for the adoption of harmonized standards in accordance with the general guidelines for cooperation between the Commission and those two bodies signed on 13 November 1984; whereas, for the purposes of this Directive, a harmonized standard is a technical specification (European standard or harmonization document) adopted by one or both of those bodies upon a remit from the Commission in accordance with Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations ⁽⁴⁾, as last amended by Directive 88/182/EEC ⁽⁵⁾, and the abovementioned general guidelines;

Whereas, pending the adoption of harmonized standards within the meaning of this Directive, conformity with the essential requirements and the free movement of appliances burning gaseous fuels should be facilitated by the acceptance, at Community level, of products conforming to the national

⁽¹⁾ OJ No C 42, 21. 2. 1989, p. 5 and OJ No C 260, 13. 10. 1989, p. 3.

⁽²⁾ OJ No C 158, 26. 6. 1989, p. 218 and Decision of 13 June 1980 (not yet published in the Official Journal).

⁽³⁾ OJ No C 194, 31. 7. 1989, p. 18.

⁽⁴⁾ OJ No L 109, 26. 4. 1983, p. 8.

⁽⁵⁾ OJ No L 81, 26. 3. 1988, p. 75.

standards whose conformity with the essential requirements has been confirmed by a Community checking procedure;

Whereas a check on compliance with the relevant technical requirements is necessary in order to provide effective protection for users and third parties; whereas the existing certification procedures differ from one Member State to another; whereas, in order to avoid multiple inspections, which are in effect barriers to the free movement of appliances burning gaseous fuels, arrangements should be made for the mutual recognition of certification procedures by the Member States; whereas, in order to facilitate mutual recognition of certification procedures, harmonized Community procedures should be set up and the criteria for appointing the bodies responsible for carrying out these procedures should be harmonized;

Whereas the Member States' responsibility on their territory for safety, health and energy conservation covered by the essential requirements must be recognized in a safeguard clause providing for an adequate Community procedure;

Whereas the addressees of any decision taken under this Directive must be informed of the reasons for such a decision and the legal remedies available to them;

Whereas the Council adopted, on 17 September 1984, a framework Directive on gas appliances (84/530/EEC)⁽¹⁾, as last amended by Directive 86/312/EEC⁽²⁾, and a separate Directive on gas water heaters (84/531/EEC)⁽³⁾, as last amended by Directive 88/665/EEC⁽⁴⁾; whereas those Directives cover the same area as this Directive and should therefore be repealed;

Whereas the measures aimed at the gradual establishment of the internal market must be adopted by 31 December 1992; whereas the internal market consists of an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Scope, placing on the market and free movement

Article 1

1. This Directive shall apply to:

- appliances burning gaseous fuels used for cooking, heating, hot water production, refrigeration, lighting or

washing and having, where applicable, a normal water temperature not exceeding 105 °C, hereinafter referred to as 'appliances'. Forced draught burners and heating bodies to be equipped with such burners will also be considered as appliances,

- safety devices, controlling devices or regulating devices and sub-assemblies, other than forced draught burners and heating bodies to be equipped with such burners separately marketed for trade use and designed to be incorporated into an appliance burning gaseous fuel or assembled to constitute such an appliance, hereinafter referred to as 'fittings'.

2. Appliances specifically designed for use in industrial processes carried out on industrial premises are excluded from the scope defined in paragraph 1.

3. For the purposes of this Directive, 'gaseous fuel' means any fuel which is in a gaseous state at a temperature of 15 °C under a pressure of 1 bar.

4. For the purposes of this Directive, an appliance is said to be 'normally used' when it is:

- correctly installed and regularly serviced in accordance with the manufacturer's instructions,
- used with a normal variation in the gas quality and a normal fluctuation in the supply pressure, and
- used in accordance with its intended purpose or in a way which can be reasonably foreseen.

Article 2

1. Member States shall take all necessary steps to ensure that the appliances referred to in Article 1 may be placed on the market and put into service only if, when normally used, they do not compromise the safety of persons, domestic animals and property.

2. Member States shall communicate the types of gas and corresponding supply pressures used on their territory to the other Member States and the Commission before 1 January 1991. They shall also communicate all changes in good time. The Commission shall ensure that this information is published in the *Official Journal of the European Communities*.

Article 3

Appliances and fittings as referred to in Article 1 shall satisfy the essential requirements applicable to them set out in Annex I.

Article 4

1. Member States may not prohibit, restrict or impede the placing on the market and the putting into service of appliances which satisfy the essential requirements of this Directive.

⁽¹⁾ OJ No L 300, 19. 11. 1984, p. 95.

⁽²⁾ OJ No L 196, 18. 7. 1986, p. 56.

⁽³⁾ OJ No L 300, 19. 11. 1984, p. 106.

⁽⁴⁾ OJ No L 382, 31. 12. 1988, p. 42.

2. Member States may not prohibit, restrict or impede the placing on the market of fittings as referred to in Article 1 accompanied by a certificate as referred to in Article 8 (4).

Article 5

1. Member States shall presume compliance with the essential requirements referred to in Article 3 of appliances and fittings when they conform to:

- (a) the national standards applicable to them implementing the harmonized standards whose reference numbers have been published in the *Official Journal of the European Communities*.

Member States shall publish the reference numbers of these national standards;

- (b) the national standards applicable to them referred to in paragraph 2 in so far as, in the areas covered by such standards, no harmonized standards exist.

2. Member States shall communicate to the Commission the texts of their national standards as referred to in paragraph 1 (b) which they regard as complying with the essential requirements referred to in Article 3. The Commission shall forward these national standards to the other Member States. In accordance with the procedure provided for in Article 6 (2), it shall notify the Member States of those national standards which are presumed to conform with the essential requirements referred to in Article 3.

Article 6

1. Where a Member State or the Commission considers that the standards referred to in Article 5 (1) do not entirely meet the essential requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the standing committee set up under Directive 83/189/EEC, hereinafter referred to as 'the committee', giving the reasons therefore. The committee shall deliver an opinion without delay.

In the light of the committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw those standards from the publications referred to in Article 5 (1).

2. After receipt of the communication referred to in Article 5 (2), the Commission shall consult the committee. Upon receipt of the latter's opinion, the Commission shall, within one month, inform the Member States whether or not the national standard(s) in question are to enjoy the presumption of conformity; if they are, the Member States shall publish the reference numbers of those standards. The Commission shall also publish them in the *Official Journal of the European Communities*.

Article 7

1. Where a Member State finds that normally used appliances bearing the EC mark might compromise the safety of persons, domestic animals or property, it shall take all appropriate measures to withdraw those appliances from the market and prohibit or restrict their being placed on the market.

The Member State concerned shall immediately inform the Commission of any such measure, indicating the reasons for its decision and, in particular, whether non-compliance is due to:

- (a) failure to meet the essential requirements referred to in Article 3, where the appliance does not correspond to the standards referred to in Article 5 (1);
- (b) incorrect application of the standards referred to in Article 5 (1);
- (c) shortcomings in the standards referred to in Article 5 (1) themselves.

2. The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that any measure as referred to in paragraph 1 is justified, it shall immediately so inform the Member State that took the measure and the other Member States.

Where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission, after consulting the parties concerned, shall bring the matter before the committee within two months if the Member State which has taken the measures intends to maintain them, and shall initiate the procedures referred to in Article 6.

3. Where an appliance which does not comply bears the EC mark, the competent Member State shall take appropriate action against whomsoever has affixed the mark and shall inform the Commission and the other Member States thereof.

4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of the procedures.

CHAPTER II

Means of certification of conformity

Article 8

1. The means of certification of conformity of series-manufactured appliances shall be:

- (a) the EC type-examination as referred to in section 1 of Annex II, and

(b) prior to their being placed on the market, at the choice of the manufacturer:

- the EC declaration of conformity to type referred to in section 2 of Annex II, or
- the EC declaration of conformity to type (guarantee of production quality) referred to in section 3 of Annex II, or
- the EC declaration of conformity to type (guarantee of product quality) referred to in section 4 of Annex II, or
- EC verification as referred to in section 5 of Annex II.

2. In the case of production of an appliance as a single unit or in small quantities, EC verification by single unit, as referred to in section 6 of Annex II, may be chosen by the manufacturer.

3. After completion of the procedures referred to in paragraphs 1 (b) and 2, the EC mark of conformity shall be affixed to conforming appliances in accordance with Article 10.

4. The procedures referred to in paragraph 1 shall be applied in respect of fittings as referred to in Article 1 with the exception of the affixing of the EC mark of conformity and, where appropriate, the drawing-up of the declaration of conformity. A certificate shall be issued declaring the conformity of the fittings with the provisions of this Directive which apply to them and stating their characteristics and how they must be incorporated into an appliance or assembled to assist compliance with the essential requirements applicable to finished appliances.

The certificate shall be supplied with the fitting.

5. Where the appliances are also subject to other Community Directives:

- their compliance with the essential requirements of this Directive shall be verified in accordance with the procedures laid down in paragraphs 1 and 2, and
- it shall be ensured that they also comply with the essential requirements of the other Directives in accordance with the procedures laid down in those Directives.

The affixing of the EC mark as referred to in paragraph 3 shall certify that the provisions of all the applicable Directives have been complied with.

6. Records and correspondence relating to the means of certification of conformity shall be drawn up in the official language(s) of the Member State where the body responsible for carrying out these procedures is established or in a language accepted by it.

Article 9

1. Each Member State shall notify the Commission and the other Member States of the bodies, hereinafter called the 'notified bodies', responsible for carrying out the procedures referred to in Article 8.

The Commission shall publish for information purposes in the *Official Journal of the European Communities* a list of the notified bodies with their identification symbols and shall ensure that the list is kept up to date.

2. Member States shall apply the criteria set out in Annex V for assessing the bodies to be notified.

Bodies which satisfy the assessment criteria laid down in the applicable harmonized standards shall be presumed to satisfy the criteria set out in that Annex.

3. A Member State which has notified a body must withdraw approval if it finds that the body no longer meets the criteria referred to in paragraph 2. It shall immediately inform the Commission and the other Member States accordingly.

CHAPTER III

EC mark of conformity

Article 10

1. The EC mark of conformity and the inscriptions set out in Annex III shall be affixed in a visible, easily legible and indelible form to the appliance or to a data plate attached to it. The data plate shall be so designed that it cannot be re-used.

2. The affixing to appliances of marks which are likely to be confused with the EC mark shall be prohibited.

Article 11

Where it is established that the EC mark has been wrongly affixed to appliances or that certification for fittings has been wrongly attributed because:

- the appliances or the fittings do not conform to the appliance or fitting as referred to in the EC type-examination certificate,
- the appliances or the fittings conform to the appliance or fitting as referred to in the EC type-examination certificate but do not meet the essential requirements applicable to them,
- the manufacturer has failed to fulfil his obligations as specified in Annex II,

the notified body shall withdraw the right to affix the EC mark or to issue the certificate and shall so inform the other notified bodies and report to the Member State concerned.

CHAPTER IV

Final provisions

Article 12

Any decision taken pursuant to this Directive which includes restriction on the placing on the market and/or putting into service of an appliance shall state the precise grounds on which it is based. It shall be notified without delay to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in the Member State in question and of the time limits to which such remedies are subject.

Article 13

Directives 84/530/EEC and 84/531/EEC are hereby repealed.

Article 14

1. Before 1 July 1991, Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive. They shall inform the Commission thereof.

They shall apply such provisions from 1 January 1992.

2. However, in derogation from Article 2, Member States may, during the period up to 31 December 1995 and without prejudice to Articles 30 to 36 of the Treaty, permit the placing on the market and/or the putting into service of appliances and fittings which comply with the regulations in force in the Member States before 1 January 1992.

3. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

Article 15

This Directive is addressed to the Member States.

Done at Luxembourg, 29 June 1990.

For the Council

The President

M. SMITH

ANNEX I

ESSENTIAL REQUIREMENTS

Preliminary remark

The obligations resulting from the essential requirements for appliances in this Annex also apply to fittings where the corresponding risk exists.

1. GENERAL CONDITIONS

1.1. Appliances must be so designed and built as to operate safely and present no danger to persons, domestic animals or property when normally used as defined in Article 1 (4) of this Directive.

1.2. When placed on the market, all appliances must:

- be accompanied by technical instructions intended for the installer,
- be accompanied by instructions for use and servicing, intended for the user,
- bear appropriate warning notices, which must also appear on the packaging.

The instructions and warning notices must be in the official language or languages of the Member States of destination.

1.2.1. The technical instructions intended for the installer must contain all the instructions for installation, adjustment and servicing required to ensure that those operations are correctly performed and that the appliance may be used safely. In particular, the instructions must specify:

- the type of gas used,
- the gas supply pressure used,
- the flow of fresh air required:
 - for the combustion air supply,
 - to avoid the formation of dangerous unburned gas mixtures for appliances not fitted with the device referred to in point 3.2.3,
- the conditions for the dispersal of combustion products,
- for forced draught burners and heating bodies intended to be equipped with such burners, their characteristics, the requirements for assembly, to assist compliance with the essential requirements applicable to finished appliances and, where appropriate, the list of combinations recommended by the manufacturer.

1.2.2. The instructions for use and servicing intended for the user must contain all the information required for safe use, and must in particular draw the user's attention to any restrictions on use.

1.2.3. The warning notices on the appliance and its packaging must clearly state the type of gas used, the gas supply pressure and any restrictions on use, in particular the restriction whereby the appliance must be installed only in areas where there is sufficient ventilation.

1.3. Fittings intended to be part of an appliance must be so designed and built as to fulfil correctly their intended purpose when incorporated in accordance with the instructions for installation.

The instructions for installation, adjustment, operation and maintenance must be provided with the fittings concerned.

2. MATERIALS

2.1. Materials must be appropriate for their intended purpose and must withstand the technical, chemical and thermal conditions to which they will foreseeably be subjected.

2.2. The properties of materials that are important for safety must be guaranteed by the manufacturer or the supplier of the appliance.

3. DESIGN AND CONSTRUCTION

3.1. General

- 3.1.1. Appliances must be so constructed that, when used normally, no instability, distortion, breakage or wear likely to impair their safety can occur.
- 3.1.2. Condensation produced at the start-up and/or during use must not affect the safety of appliances.
- 3.1.3. Appliances must be so designed and constructed as to minimize the risk of explosion in the event of a fire of external origin.
- 3.1.4. Appliances must be so constructed that water and inappropriate air penetration into the gas circuit does not occur.
- 3.1.5. In the event of a normal fluctuation of auxiliary energy, appliances must continue to operate safely.
- 3.1.6. Abnormal fluctuation or failure of auxiliary energy or its restoration must not lead to an unsafe situation.
- 3.1.7. Appliances must be so designed and constructed as to obviate hazards of electrical origin. In the area in which it applies, compliance with the safety objectives in respect of electrical hazards laid down in Directive 73/23/EEC ⁽¹⁾ shall be equivalent to fulfilment of this requirement.
- 3.1.8. All pressurized parts of an appliance must withstand the mechanical and thermal stresses to which they are subjected without any deformation affecting safety.
- 3.1.9. Appliances must be so designed and constructed that failure of a safety, controlling or regulating device may not lead to an unsafe situation.
- 3.1.10. If an appliance is equipped with safety and controlling devices, the functioning of the safety devices must not be overruled by that of the controlling devices.
- 3.1.11. All parts of appliances which are set or adjusted at the stage of manufacture and which should not be manipulated by the user or the installer must be appropriately protected.
- 3.1.12. Levers and other controlling and setting devices must be clearly marked and give appropriate instructions so as to prevent any error in handling. Their design must be such as to preclude accidental manipulation.

3.2. Unburned gas release

- 3.2.1. Appliances must be so constructed that the gas leakage rate is not dangerous.
- 3.2.2. Appliances must be so constructed that gas release during ignition and re-ignition and after flame extinction is limited in order to avoid a dangerous accumulation of unburned gas in the appliance.
- 3.2.3. Appliances intended to be used in indoor spaces and rooms must be fitted with a special device which avoids a dangerous accumulation of unburned gas in such spaces or rooms.

Appliances which are not fitted with such devices must be used only in areas where there is sufficient ventilation to avoid a dangerous accumulation of unburned gas.

Member States may define on their territory adequate space ventilation conditions for the installation of such appliances, bearing in mind the features peculiar to them.

Large-scale kitchen appliances and appliances powered by gas containing toxic components must be equipped with the aforesaid device.

3.3. Ignition

Appliances must be so constructed that, when used normally:

- ignition and re-ignition is smooth,
- cross-lighting is assured.

3.4. Combustion

- 3.4.1. Appliances must be so constructed that, when used normally, flame stability is assured and combustion products do not contain unacceptable concentrations of substances harmful to health.

⁽¹⁾ OJ No L 77, 26. 3. 1973, p. 29.

- 3.4.2. Appliances must be so constructed that, when used normally, there will be no accidental release of combustion products.
 - 3.4.3. Appliances connected to a flue for the dispersal of combustion products must be so constructed that in abnormal draught conditions there is no release of combustion products in a dangerous quantity into the room concerned.
 - 3.4.4. Independent flueless domestic heating appliances and flueless instantaneous water heaters must not cause, in the room or space concerned, a carbon monoxide concentration likely to present a danger to the health of persons exposed, bearing in mind the foreseeable duration of their exposure.
 - 3.5. **Rational use of energy**
Appliances must be so constructed as to ensure rational use of energy, reflecting the state of the art and taking into account safety aspects.
 - 3.6. **Temperatures**
 - 3.6.1. Parts of appliances which are intended to be placed in close proximity to the floor or other surfaces must not reach temperatures which present a danger in the surrounding area.
 - 3.6.2. The surface temperature of knobs and levers of appliances intended to be manipulated must not present a danger to the user.
 - 3.6.3. The surface temperatures of external parts of appliances intended for domestic use, with the exception of surfaces or parts which are associated with the transmission of heat, must not under operating conditions present a danger to the user and in particular to children, for whom an appropriate reaction time must be taken into account.
 - 3.7. **Foodstuffs and water used for sanitary purposes**
Without prejudice to the Community rules in this area, materials and components used in the construction of an appliance, which may come into contact with food or water used for sanitary purposes, must not impair their quality.
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ANNEX II

PROCEDURE FOR CERTIFICATION OF CONFORMITY

1. EC TYPE-EXAMINATION

1.1. The EC type-examination is that part of the procedure by which a notified body checks and certifies that an appliance, representative of the production envisaged, meets the provisions of this Directive which apply to it.

1.2. The application for type-examination must be lodged by the manufacturer or his authorized representative established within the Community with a single notified body.

1.2.1. The application must include:

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address,
- a written declaration that the application has not been lodged with any other notified body,
- the design documentation, as described in Annex IV.

1.2.2. The manufacturer must place at the disposal of the notified body an appliance, representative of the production envisaged, hereinafter called 'type'. The notified body may request further samples of the type if needed for the test programme.

The type may additionally cover variants of the product provided that those variants do not have different characteristics with respect to types of risk.

1.3. The notified body must:

1.3.1. examine the design documentation and verify that the type has been manufactured in conformity with the design documentation and identify the elements which have been designed in accordance with the applicable provisions of the standards referred to in Article 5 and the essential requirements of this Directive;

1.3.2. perform, or have performed, the appropriate examinations and/or tests to check whether the solutions adopted by the manufacturer meet the essential requirements where the standards referred to in Article 5 have not been applied;

1.3.3. perform, or have performed, the appropriate examinations and/or tests to check whether the applicable standards have effectively been applied where the manufacturer has chosen to do so, thereby assuring conformity with the essential requirements.

1.4. Where the type satisfies the provisions of this Directive, the notified body must issue an EC type-examination certificate to the applicant. The certificate must contain the conclusions of the examination, the conditions, if any, for its validity and the necessary data for identification of the approved type and, if relevant, descriptions of its functioning. Relevant technical elements such as drawings and diagrams must be annexed to the certificate.

1.5. The notified body must inform the other notified bodies forthwith of the issuing of the EC type-examination certificate and any additions to the said type as referred to in point 1.7. They may obtain a copy of the EC type-examination certificate and/or its additions and on a reasoned request may obtain a copy of the Annexes to the certificate and the reports on the examinations and tests carried out.

1.6. A notified body which refuses to issue or withdraws an EC type-examination certificate must inform the Member State which notified it and the other notified bodies accordingly, giving the reasons for its decision.

1.7. The applicant must keep the notified body that has issued the EC type-examination certificate informed of all modifications to the approved type which might affect conformity with the essential requirements.

Modifications to the approved type must receive additional approval from the notified body that issued the EC type-examination certificate where such changes affect conformity with the essential requirements or the prescribed conditions for use of the appliance. This additional approval is to be given in the form of an addition to the original EC type-examination certificate.

2. EC DECLARATION OF CONFORMITY TO TYPE

- 2.1. The EC declaration of conformity to type is that part of the procedure whereby the manufacturer declares that the appliances concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the essential requirements of this Directive which apply to them. The manufacturer must affix the EC mark on each appliance and draw up a written declaration of conformity. The declaration of conformity may cover one or more appliances and must be kept by the manufacturer. The EC mark must be accompanied by the identification symbol of the notified body responsible for the random checks set out in point 2.3.
- 2.2. The manufacturer must take all necessary measures to ensure that the manufacturing process, including final product inspection and testing, results in homogeneity of production and conformity of the appliances with the type as described in the EC type-examination certificate and with the requirements of this Directive which apply to them. A notified body, chosen by the manufacturer, must carry out random checks on the appliances as set out in point 2.3.
- 2.3. On-site checks of appliances must be undertaken at random by the notified body at intervals of one year or less. An adequate number of appliances must be examined and appropriate tests as set out in the applicable standards referred to in Article 5 or equivalent tests must be carried out in order to ensure conformity with the corresponding essential requirements of this Directive. The notified body shall in each case determine whether these tests need to be carried out in full or in part. Where one or more appliances are rejected, the notified body shall take the appropriate measures to prevent the marketing thereof.

3. EC DECLARATION OF CONFORMITY TO TYPE (guarantee of production quality)

- 3.1. The EC declaration of conformity to type (guarantee of production quality) is the procedure whereby a manufacturer who fulfils the obligations in point 3.2 declares that the appliances concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the essential requirements of this Directive which applies to them. The manufacturer must affix the EC mark to each appliance and draw up a written declaration of conformity. This declaration may cover one or more appliances and must be kept by the manufacturer. The EC mark must be accompanied by the identification symbol of the notified body responsible for EC surveillance.
- 3.2. The manufacturer shall apply a quality system that ensures conformity of the appliances with the type as described in the EC type-examination certificate and with the essential requirements of this Directive which apply to them. The manufacturer is subject to EC surveillance as specified in point 3.4.
- 3.3. **Quality system**
- 3.3.1. The manufacturer must lodge an application for approval of his quality system with a notified body of his choice for the appliances in question.
- The application must include:
- the quality system documentation,
 - an undertaking to carry out the obligations arising from the quality system as approved,
 - an undertaking to maintain the approved quality system to ensure its continuing suitability and effectiveness,
 - documentation relating to the approved type and a copy of the EC type-examination certificate.
- 3.3.2. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and logical manner in the form of measures, procedures and written instructions. This quality system documentation must permit a uniform interpretation of the quality programmes, plans, manuals and records. It shall contain, in particular, an adequate description of:
- the quality objectives, the organizational structure and responsibilities of management and of their powers with regard to appliance quality,
 - the manufacturing processes, quality control and quality assurance techniques and systematic actions that will be used,

- the examinations and tests that will be carried out before, during and after manufacture and the frequency with which they will be carried out,
 - the method of monitoring attainment of the required appliance quality and the effective operation of the quality system.
- 3.3.3. The notified body shall examine and evaluate the quality system to determine whether it satisfies the requirements referred to in point 3.3.2. It will presume conformity with these requirements in respect of quality systems that implement the corresponding harmonized standard.
- It must notify its decision to the manufacturer and inform the other notified bodies thereof. The notification to the manufacturer must contain the conclusions of the examination, the name and address of the notified body and the reasoned assessment decision in respect of the appliances concerned.
- 3.3.4. The manufacturer must keep the notified body that has approved the quality system informed of any updating of the quality system in relation to changes brought about by, for example, new technologies and quality concepts.
- The notified body must examine the proposed modifications and decide whether the modified quality system complies with the relevant provisions or whether reappraisal is necessary. It must notify the manufacturer of its decision. The notification must include the conclusions of the inspection and the reasoned assessment decision.
- 3.3.5. A notified body that withdraws approval of a quality system must so inform the other notified bodies, giving the reasons for the decision.
- 3.4. EC surveillance
- 3.4.1. The purpose of EC surveillance is to ensure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 3.4.2. The manufacturer must allow the notified body access for inspection purposes to the place of manufacture, inspection, testing and storage and must provide it with all necessary information, in particular:
- the quality system documentation,
 - the quality records, such as inspection reports and test data, calibration data, reports on qualifications of the staff concerned, etc.
- 3.4.3. The notified body must carry out a check at least once every two years to ensure that the manufacturer is maintaining and applying the approved quality system and must supply a report of the check to the manufacturer.
- 3.4.4. Furthermore, the notified body may make unannounced visits to the manufacturer. During these visits, the notified body may carry out tests on appliances or have them carried out. It must supply the manufacturer with an inspection report and, if appropriate, a test report.
- 3.4.5. The manufacturer may supply the notified body's report on request.
4. EC DECLARATION OF TYPE CONFORMITY (guarantee of product quality)
- 4.1. The EC declaration of type conformity (guarantee of product quality) is that part of the procedure whereby a manufacturer who fulfils the obligations in point 4.2 declares that the appliances concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the essential requirements of this Directive which apply to them. The manufacturer must affix the EC mark to each appliance and draw up a written declaration of conformity. This declaration may cover one or more appliances and must be kept by the manufacturer. The EC mark must be accompanied by the identification symbol of the notified body responsible for EC surveillance.
- 4.2. The manufacturer shall apply an approved quality system for the final inspection of the appliances and the tests, as specified in point 4.3, and is subject to EC surveillance as specified in point 4.4.
- 4.3. Quality system
- 4.3.1. Under this procedure, the manufacturer must lodge an application for approval of his quality system with a notified body of his choice for the appliances in question.
- The application must include:
- the quality system documentation,
 - an undertaking to carry out the obligations arising from the quality system as approved,

- an undertaking to maintain the approved quality system to ensure its continuing suitability and effectiveness,
- the documentation relating to the approved type and a copy of the EC type-examination certificate.

- 4.3.2. As part of the quality system, each appliance must be examined and appropriate tests as laid down in the applicable standard(s) referred to in Article 5 or equivalent tests carried out to check its conformity with the essential requirements relating to it in this Directive.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and logical manner in the form of measures, procedures and written instructions. This quality system documentation must permit a uniform interpretation of the quality programmes, plans, manuals and records.

The quality system documentation shall contain, in particular, an adequate description of:

- the quality objectives, the organizational structure and responsibilities of management and of their powers with regard to appliance quality,
- the checks and tests to be carried out after manufacture,
- the method of verifying the effective operation of the quality system.

- 4.3.3. The notified body shall examine and evaluate the quality system to determine whether it satisfies the requirements referred to in point 4.3.2. It will presume conformity with these requirements in respect of quality systems that implement the corresponding harmonized standard. It must notify the manufacturer of its decision and inform the other notified bodies thereof. The notification to the manufacturer must contain the conclusions of the examination, the name and address of the notified body and the reasoned assessment decision for the appliances concerned.

- 4.3.4. The manufacturer must keep the notified body which approved the quality system informed of any adaptation of the quality system made necessary, e.g. by new technology and quality concepts.

The notified body must examine the proposed changes and decide whether the amended quality system satisfies the relevant provisions or whether a reassessment is necessary. It must notify the manufacturer of its decision. The notification must contain the conclusions of the inspection and the reasoned assessment decision.

- 4.3.5. A notified body which withdraws approval of a quality system must inform the other notified bodies that it has done so and give reasons for its decision.

4.4. EC surveillance

- 4.4.1. The purpose of EC surveillance is to ensure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 4.4.2. The manufacturer must allow the notified body access for inspection to the place of inspection, testing and storage and must provide it with all necessary information, in particular:

- the quality system documentation,
- the quality files such as inspection reports and test data, calibration data, report on qualifications of the staff concerned, etc.

- 4.4.3. The notified body must carry out a check at least once every two years to ensure that the manufacturer is maintaining and applying the approved quality system and must supply a report on the check to the manufacturer.

- 4.4.4. Furthermore, the notified body may make unannounced visits to the manufacturer. During these visits, the body may carry out tests on appliances or have them carried out. It must supply the manufacturer with an inspection report and, if appropriate, a test report.

- 4.4.5. The manufacturer may supply the notified body's report on request.

5. EC VERIFICATION

- 5.1. EC verification is that part of the procedure whereby a notified body checks and certifies that the appliances are in conformity with the type as described in the EC type-approval certificate and satisfy the essential requirements of this Directive which apply to them.

- 5.2. EC verification may, at the choice of the manufacturer, be carried out by checking and testing each appliance as specified in point 5.3 or by checking and testing the appliance on a statistical basis as specified in point 5.4.
- 5.3. **Verification by checking and testing each appliance**
- 5.3.1. Each appliance must be examined and appropriate tests as defined in the relevant standards referred to in Article 5 or equivalent tests must be carried out in order to check its conformity with the relevant essential requirements of this Directive.
- 5.3.2. The notified body must affix the EC mark on each approved appliance and draw up a written certificate of conformity. The certificate may cover one or more appliances and is kept by the manufacturer. The EC mark must be accompanied by the identification symbol of the notified body.
- 5.4. **Statistical verification**
- 5.4.1. The manufacturer must submit his appliances in the form of homogeneous batches and take all necessary measures to ensure that the manufacturing process results in the homogeneity of each product batch.
- 5.4.2. Where appropriate, the manufacturer may affix the EC mark on each appliance during the manufacturing process. The EC mark must be accompanied by the identification symbol of the notified body responsible for the statistical verification.
- 5.4.3. Appliances must be subject to statistical control by attributes. They should be grouped into identifiable batches consisting of units of a single model which are manufactured under the same conditions. At random intervals a batch is examined. The appliances constituting a sample are examined individually and appropriate tests as laid down in the applicable standard(s) referred to in Article 5 or equivalent tests are carried out to determine whether the batch is to be accepted or rejected.
- A sampling plan with the following operating characteristics is applied:
- a standard quality level corresponding to a 95 % probability of acceptance with a percentage of non-conformity between 0,5 and 1,5 %,
 - a limit quality corresponding to a 5 % probability of acceptance with a percentage of non-conformity between 5 and 10 %.
- 5.4.4. If a batch is accepted, the notified body must draw up a written certificate of conformity which is kept by the manufacturer. All the appliances in the batch may be placed on the market, except those in the sample which have been identified as not conforming.
- If a batch is rejected, the competent notified body must take the appropriate measures to prevent its being placed on the market. Should batches be rejected frequently, the notified body may suspend statistical verification.
6. **EC VERIFICATION BY UNIT**
- 6.1. EC verification by unit is the procedure whereby a notified body checks and certifies that an appliance is in conformity with the requirements of this Directive which apply to it. The notified body must affix the EC mark on the appliance and draw up a written certificate of conformity.
- The certificate is kept by the manufacturer.
- 6.2. The design documentation referred to in Annex IV must be made available to the notified body.
- 6.3. The appliance must be examined and appropriate tests taking account of the design documentation carried out in order to ensure conformity of the appliance with the essential requirements of this Directive.
- If deemed necessary by the notified body, the examinations and the appropriate tests may be carried out after installation of the appliance.

*ANNEX III***EC MARK AND INSCRIPTIONS**

1. The EC mark consists of the symbol CE as shown below, followed by the last two digits of the year in which the mark was affixed and the identification symbol of the notified body that has carried out the random checks, EC surveillance or EC verification.
2. The appliance or its data plate must bear the EC mark together with the following inscriptions:
 - the manufacturer's name or identification symbol,
 - the trade name of the appliance,
 - the type of electrical supply used, if applicable,
 - the appliance category.

Information needed for installation purposes may be added according to the nature of the appliance.



ANNEX IV**DESIGN DOCUMENTATION**

The design documentation must contain the following information, in so far as is required by the notified body for assessment:

- a general description of the appliance,
- conceptual designs and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of the above, including the operation of the appliances,
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements where the standards referred to in Article 5 have not been applied,
- test reports,
- manuals for installation and use.

Where appropriate, the design documentation must contain the following elements:

- attestations relating to the equipment incorporated in the appliance,
- attestations and certificates relating to the methods of manufacture and/or inspection and/or monitoring of the appliance,
- any other document making it possible for the notified body to improve its assessment.

ANNEX V**MINIMUM CRITERIA FOR ASSESSMENT OF NOTIFIED BODIES**

The notified bodies designated by the Member States must fulfil the following minimum conditions:

- availability of personnel and of the necessary means and equipment,
- technical competence and professional integrity of personnel,
- independence in carrying out tests, preparing reports, issuing certificates and performing the surveillance provided for in this Directive, of management and technical staff in relation to all circles, groups or persons directly or indirectly involved in the field of the appliances,
- maintenance of professional secrecy by staff,
- possession of civil liability insurance unless that liability is covered by the State under national law.

Fulfilment of the conditions in the first two indents must be periodically verified by the competent authorities of the Member States or by bodies designated by the Member States.
