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Contents

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

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

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 23 April 1990

on the contained use of genetically modified micro-organisms

(90/219/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 130s thereof,

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

Having regard to the opinion of the European Parliament (2),

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

Whereas, under the Treaty, action by the Community relating to the environment shall be based on the principle that preventive action shall be taken and shall have as its objective to preserve, protect and improve the environment and to protect human health;

Whereas the Council Resolution of 19 October 1987 (4) concerning the Fourth Environmental Action Programme of the European Communities declares that measures concerning the evaluation and best use of biotechnology with regard to the environment are a priority area on which Community action should concentrate;

Whereas the development of biotechnology is such as to contribute to the economic expansion of the Member States; whereas this implies that genetically modified micro-organisms will be used in operations of various types and scale;

Whereas the contained use of genetically modified micro-organisms should be carried out in such way as to limit their possible negative consequences for human health and the environment, due attention being given to the prevention of accidents and the control of wastes;

Whereas micro-organisms, if released in the environment in one Member State in the course of their contained use, may reproduce and spread, crossing national frontiers and thereby affecting other Member States;

Whereas, in order to bring about the safe development of biotechnology throughout the Community, it is necessary to establish common measures for the evaluation and reduction of the potential risks arising in the course of all operations involving the contained use of genetically modified micro-organisms and to set appropriate conditions of use;

Whereas the precise nature and scale of risks associated with genetically modified micro-organisms are not yet fully known and the risk involved must be assessed case by case; whereas, to evaluate risk for human health and the environment, it is necessary to lay down requirements for risk assessment;

Whereas genetically modified micro-organisms should be classified in relation to the risks they present; whereas criteria should be provided for this purpose; whereas particular attention should be given to operations using the more hazardous genetically modified micro-organisms;

Whereas appropriate containment measures should be applied at the various stages of an operation to control emissions and to prevent accidents;

(1) OJ No C 198, 28. 7. 1988, p. 9 and OJ No C 246, 27. 9. 1989, p. 6.
(2) OJ No C 158, 26. 6. 1989, p. 122 and OJ No C 96, 17. 4. 1990.
(3) OJ No C 23, 30. 1. 1989, p. 45.
(4) OJ No C 328, 7. 12. 1987, p. 1.

Whereas any person, before undertaking for the first time the contained use of a genetically modified micro-organism in a particular installation, should forward to the competent authority a notification so that the authority may satisfy itself that the proposed installation is appropriate to carry out the activity in a manner that does not present a hazard to human health and the environment;

Whereas it is also necessary to establish appropriate procedures for the case-by-case notification of specific operations involving the contained use of genetically modified micro-organisms, taking account of the degree of risk involved;

Whereas, in the case of operations involving high risk, the consent of the competent authority should be given;

Whereas it may be considered appropriate to consult the public on the contained use of genetically modified micro-organisms;

Whereas appropriate measures should be taken to inform any person liable to be affected by an accident on all matters relating to safety;

Whereas emergency plans should be established to deal effectively with accidents;

Whereas, if an accident occurs, the user should immediately inform the competent authority and communicate the information necessary for assessing the impact of that accident and for taking the appropriate action;

Whereas it is appropriate for the Commission, in consultation with the Member States, to establish a procedure for the exchange of information on accidents and for the Commission to set up a register of such accidents;

Whereas the contained use of genetically modified micro-organisms throughout the Community should be monitored and to this end Member States should supply certain information to the Commission;

Whereas a committee should be set up to assist the Commission on matters relating to the implementation of this Directive and to its adaptation to technical progress,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive lays down common measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment.

Article 2

For the purposes of this Directive:

(a) 'micro-organism' shall mean any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material;

(b) 'genetically modified micro-organism' shall mean a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Within the terms of this definition:

(i) genetic modification occurs at least through the use of the techniques listed in Annex I A, Part 1;

(ii) the techniques listed in Annex I A, Part 2, are not considered to result in genetic modification;

(c) 'contained use' shall mean any operation in which micro-organisms are genetically modified or in which such genetically modified micro-organisms are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers, or a combination of physical barriers together with chemical and/or biological barriers, are used to limit their contact with the general population and the environment;

(d) Type A operation shall mean any operation used for teaching, research, development, or non-industrial or non-commercial purposes and which is of a small scale (e.g. 10 litres culture volume or less);

(e) Type B operation shall mean any operation other than a Type A operation;

(f) 'accident' shall mean any incident involving a significant and unintended release of genetically modified micro-organisms in the course of their contained use which could present an immediate or delayed hazard to human health or the environment;

(g) 'user' shall mean any natural or legal person responsible for the contained use of genetically modified micro-organisms;

(h) 'notification' shall mean the presentation of documents containing the requisite information to the competent authorities of a Member State.

Article 3

This Directive shall not apply where genetic modification is obtained through the use of the techniques listed in Annex I B.

Article 4

1. For the purposes of this Directive, genetically modified micro-organisms shall be classified as follows:

Group I: those satisfying the criteria of Annex II;

Group II: those other than in Group I.

2. For Type A operations, some of the criteria in Annex II may not be applicable in determining the classification of a particular genetically modified micro-organism. In such a case, the classification shall be provisional and the competent authority shall ensure that relevant criteria are used with the aim of obtaining equivalence as far as possible.

3. Before this Directive is implemented, the Commission shall draw up guidelines for classification under the procedures of Article 21.

Article 5

Articles 7 to 12 shall not apply to the transport of genetically modified micro-organisms by road, rail, inland waterway, sea or air. This Directive shall not apply to the storage, transport, destruction or disposal of genetically modified micro-organisms which have been placed on the market under Community legislation, which includes a specific risk assessment similar to that provided in this Directive.

Article 6

1. Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the contained use of genetically modified micro-organisms.

2. To this end, the user shall carry out a prior assessment of the contained uses as regards the risks to human health and the environment that they may incur.

3. In making such an assessment the user shall, in particular, take due account of the parameters set out in Annex III, as far as they are relevant, for any genetically modified micro-organisms he is proposing to use.

4. A record of this assessment shall be kept by the user and made available in summary form to the competent authority as part of the notification under Articles 8, 9 and 10 or upon request.

Article 7

1. For genetically modified micro-organisms in Group I, principles of good microbiological practice, and the following principles of good occupational safety and hygiene, shall apply:

(i) to keep workplace and environmental exposure to any physical, chemical or biological agent to the lowest practicable level;

(ii) to exercise engineering control measures at source and to supplement these with appropriate personal protective clothing and equipment when necessary;

(iii) to test adequately and maintain control measures and equipment;

(iv) to test, when necessary, for the presence of viable process organisms outside the primary physical containment;

(v) to provide training of personnel;

(vi) to establish biological safety committees or subcommittees as required;

(vii) to formulate and implement local codes of practice for the safety of personnel.

2. In addition to these principles, the containment measures set out in Annex IV shall be applied, as appropriate, to contained uses of genetically modified micro-organisms in Group II so as to ensure a high level of safety.

3. The containment measures applied shall be periodically reviewed by the user to take into account new scientific or technical knowledge relative to risk management and treatment and disposal of wastes.

Article 8

When a particular installation is to be used for the first time for operations involving the contained use of genetically modified micro-organisms, the user shall be required to submit to the competent authorities, before commencing such use, a notification containing at least the information listed in Annex V A.

A separate notification shall be made for first use of genetically modified micro-organisms in Group I and Group II respectively.

Article 9

1. Users of genetically modified micro-organisms classified in Group I in Type A operations shall be required to keep records of the work carried out which shall be made available to the competent authority on request.

2. Users of genetically modified micro-organisms classified in Group I in Type B operations shall, before commencing the contained use, be required to submit to the competent authorities a notification containing the information listed in Annex V B.

Article 10

1. Users of genetically modified micro-organisms classified in Group II in Type A operations shall, before commencing the contained use, be required to submit to the competent authorities a notification containing the information listed in Annex V C.

2. Users of genetically modified micro-organisms classified in Group II in Type B operations shall, before commencing the contained use, be required to submit to the competent authorities a notification containing:

— information on the genetically modified micro-organism(s),

— information on personnel and training,

— information on the installation,

— information on waste management,

— information on accident prevention and emergency response plans,

— the assessment of the risks to human health and the environment referred to in Article 6,

the details of which are listed in Annex V D.

Article 11

1. Member States shall designate the authority or authorities competent to implement the measures which they adopt in application of this Directive and to receive and acknowledge the notifications referred to in Article 8, Article 9 (2) and Article 10.

2. The competent authorities shall examine the conformity of the notifications with the requirements of this Directive, the accuracy and completeness of the information given, the correctness of the classification and, where appropriate, the adequacy of the waste management, safety, and emergency response measures.

3. If necessary, the competent authority may:

(a) ask the user to provide further information or to modify the conditions of the proposed contained use. In this case the proposed contained use cannot proceed until the competent authority has given its approval on the basis of the further information obtained or of the modified conditions of the contained use;

(b) limit the time for which the contained use should be permitted or subject it to certain specific conditions.

4. In the case of first-time use in an installation as referred to in Article 8:

— where such use involves genetically modified micro-organisms in Group I, the contained use may, in the absence of any indication to the contrary from the competent authority, proceed 90 days after submission of the notification, or earlier with the agreement of the competent authority;

— where such use involves genetically modified micro-organisms in Group II, the contained use may not proceed without the consent of the competent authority. The competent authority shall communicate its decision in writing at the latest 90 days after submission of the notification.

5. (a) Operations notified under Article 9 (2) and Article 10 (1), may, in the absence of any indication to the contrary from the competent authority, proceed 60 days after submission of the notification, or earlier with the agreement of the competent authority.

(b) Operations notified under Article 10 (2) may not proceed without the consent of the competent authority. The competent authority shall communicate its decision in writing at the latest 90 days after submission of the notification.

6. For the purpose of calculating the periods referred to in paragraphs 4 and 5, any periods of time during which the competent authority:

— is awaiting any further information which it may have requested from the notifier in accordance with paragraph 3 (a) or

— is carrying out a public inquiry or consultation in accordance with Article 13

shall not be taken into account.

Article 12

1. If the user becomes aware of relevant new information or modifies the contained use in a way which could have significant consequences for the risks posed by the contained use, or if the category of genetically modified micro-organisms used is changed, the competent authority shall be informed as soon as possible and the notification under Articles 8, 9 and 10 modified.

2. If information becomes available subsequently to the competent authority which could have significant consequences for the risks posed by the contained use, the competent authority may require the user to modify the conditions of, suspend or terminate the contained use.

Article 13

Where a Member State considers it appropriate, it may provide that groups or the public shall be consulted on any aspect of the proposed contained use.

Article 14

The competent authorities shall ensure that, where necessary, before an operation commences:

(a) an emergency plan is drawn up for the protection of human health and the environment outside the installation in the event of an accident and the emergency services are aware of the hazards and informed thereof in writing;

(b) information on safety measures and on the correct behaviour to adopt in the case of an accident is supplied in an appropriate manner, and without their having to request it, to persons liable to be affected by the accident. The information shall be repeated and updated at appropriate intervals. It shall also be made publicly available.

The Member States concerned shall at the same time make available to other Member States concerned, as a basis for all necessary consultation within the framework of their bilateral relations, the same information as that which is disseminated to their nationals.

Article 15

1. Member States shall take the necessary measures to ensure that, in the event of an accident, the user shall be required immediately to inform the competent authority specified in Article 11 and provide the following information:

— the circumstances of the accident,

— the identity and quantities of the genetically modified micro-organisms released,

— any information necessary to assess the effects of the accident on the health of the general population and the environment,

— the emergency measures taken.

2. Where information is given under paragraph 1, the Member States shall be required to:

— ensure that any emergency, medium and long-term measures necessary are taken, and immediately alert any Member State which could be affected by the accident;

— collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit the effects thereof.

Article 16

1. Member States shall be required to:

(a) consult with other Member States liable to be affected in the event of an accident in the drawing up and implementation of emergency plans;

(b) inform the Commission as soon as possible of any accident within the scope of this Directive, giving details of the circumstances of the accident, the identity and quantities of the genetically modified micro-organisms released, the emergency response measures employed and their effectiveness, and an analysis of the accident including recommendations to limit its effects and avoid similar accidents in the future.

2. The Commission, in consultation with the Member States, shall establish a procedure for the exchange of information under paragraph 1. It shall also set up and keep at the disposal of the Member States a register of accidents within the scope of this Directive which have occurred, including an analysis of the causes of the accidents, experience gained and measures taken to avoid similar accidents in the future.

Article 17

Member States shall ensure that the competent authority organizes inspections and other control measures to ensure user compliance with this Directive.

Article 18

1. Member States shall send to the Commission, at the end of each year, a summary report on the contained uses notified under Article 10 (2) including the description, proposed uses and risks of the genetically modified micro-organisms.

2. Every three years, Member States shall send the Commission a summary report on their experience with this Directive, the first time being on 1 September 1992.

3. Every three years, the Commission shall publish a summary based on the reports referred to in paragraph 2, the first time being in 1993.

4. The Commission may publish general statistical information on the implementation of this Directive and related matters, as long as it contains no information likely to cause harm to the competitive position of a user.

Article 19

1. The Commission and the competent authorities shall not divulge to third parties any confidential information notified or otherwise provided under this Directive and shall protect intellectual property rights relating to the data received.

2. The notifier may indicate the information in the notifications submitted under this Directive, the disclosure of which might harm his competitive position, that should be treated as confidential. Verifiable justification must be given in such cases.

3. The competent authority shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decision.

4. In no case may the following information, when submitted according to Articles 8, 9 or 10, be kept confidential:

— description of the genetically modified micro-organisms, name and address of the notifier, purpose of the contained use, and location of use;

— methods and plans for monitoring of the genetically modified micro-organisms and for emergency response;

— the evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects.

5. If, for whatever reasons, the notifier withdraws the notification, the competent authority must respect the confidentiality of the information supplied.

Article 20

Amendments necessary to adapt Annexes II to V to technical progress shall be decided in accordance with the procedure defined in Article 21.

Article 21

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

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

(b) If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

Article 22

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 23 October 1991. They shall forthwith inform the Commission thereof.

Article 23

This Directive is addressed to the Member States.

Done at Luxembourg, 23 April 1990.

For the Council

The President

A. REYNOLDS

ANNEX I A

PART 1

Techniques of genetic modification referred to in Article 2 (b) (i) are, *inter alia:*

(i) recombinant DNA techniques using vector systems as previously covered by Recommendation 82/472/EEC [1];

(ii) techniques involving the direct introduction into a micro-organism of heritable material prepared outside the micro-organism including micro-injection, macro-injection and micro-encapsulation;

(iii) cell fusion or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART 2

Techniques referred to in Article 2 (b) (ii) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant-DNA molecules or genetically modified organisms:

(1) *in vitro* fertilization;

(2) conjugation, transduction, transformation or any other natural process;

(3) polyploidy induction.

ANNEX I B

Techniques of genetic modification to be excluded from the Directive, on condition that they do not involve the use of genetically modified micro-organisms as recipient or parental organisms:

(1) mutagenesis;

(2) the construction and use of somatic animal hybridoma cells (e.g. for the production of monoclonal antibodies);

(3) cell fusion (including protoplast fusion) of cells from plants which can be produced by traditional breeding methods;

(4) self-cloning of non-pathogenic naturally occurring micro-organisms which fulfil the criteria of Group I for recipient micro-organisms.

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[1] OJ No 213, 21. 7. 1982, p. 15.

ANNEX II

CRITERIA FOR CLASSIFYING GENETICALLY MODIFIED MICRO-ORGANISMS IN GROUP I

A. **Recipient or parental organism**

— non-pathogenic;

— no adventitious agents;

— proven and extended history of safe use or built-in biological barriers, which, without interfering with optimal growth in the reactor or fermentor, confer limited survivability and replicability, without adverse consequences in the environment.

B. **Vector/Insert**

— well characterized and free from known harmful sequences;

— limited in size as much as possible to the genetic sequences required to perform the intended function;

— should not increase the stability of the construct in the environment (unless that is a requirement of intended function);

— should be poorly mobilizable;

— should not transfer any resistance markers to micro-organisms not known to acquire them naturally (if such acquisition could compromise use of drug to control disease agents).

C. **Genetically modified micro-organisms**

— non-pathogenic;

— as safe in the reactor or fermentor as recipient or parental organism, but with limited survivability and/or replicability without adverse consequences in the environment.

D. **Other genetically modified micro-organisms that could be included in Group I if they meet the conditions in C above**

— those constructed entirely from a single prokaryotic recipient (including its indigenous plasmids and viruses) or from a single eukaryotic recipient (including its chloroplasts, mitochondria, plasmids, but excluding viruses);

— those that consist entirely of genetic sequences from different species that exchange these sequences by known physiological processes.

ANNEX III

SAFETY ASSESSMENT PARAMETERS TO BE TAKEN INTO ACCOUNT, AS FAR AS THEY ARE RELEVANT, IN ACCORDANCE WITH ARTICLE 6 (3)

A. Characteristics of the donor, recipient or (where appropriate) parental organism(s)

B. Characteristics of the modified micro-organism

C. Health considerations

D. Environmental considerations

A. Characteristics of the donor, recipient or (where appropriate) parental organism(s)

— names and designation;

— degree of relatedness;

— sources of the organism(s);

— information on reproductive cycles (sexual/asexual) of the parental organism(s) or, where applicable, of the recipient micro-organism;

— history of prior genetic manipulations;

— stability of parental or of recipient organism in terms of relevant genetic traits;

— nature of pathogenicity and virulence, infectivity, toxicity and vectors of disease transmission;

— nature of indigenous vectors:

sequence,

frequency of mobilization,

specificity,

presence of genes which confer resistance;

— host range;

— other potentially significant physiological traits;

— stability of these traits;

— natural habitat and geographic distribution. Climatic characteristics of original habitats;

— significant involvement in environmental processes (such as nitrogen fixation or pH regulation);

— interaction with, and effects on, other organisms in the environment (including likely competitive or symbiotic properties);

— ability to form survival structures (such as spores or sclerotia).

B. Characteristics of the modified micro-organism

— the description of the modification including the method for introducing the vector-insert into the recipient organism or the method used for achieving the genetic modification involved;

— the function of the genetic manipulation and/or of the new nucleic acid;

— nature and source of the vector;

— structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified micro-organism;

— stability of the micro-organism in terms of genetic traits;

— frequency of mobilization of inserted vector and/or genetic transfer capability;

— rate and level of expression of the new genetic material. Method and sensitivity of measurement;

— activity of the expressed protein.

C. **Health considerations**

— toxic or allergenic effects of non-viable organisms and/or their metabolic products;

— product hazards;

— comparison of the modified micro-organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

— capacity for colonization;

— if the micro-organism is pathogenic to humans who are immunocompetent:

(a) diseases caused and mechanism of pathogenicity including invasiveness and virulence;

(b) communicability;

(c) infective dose;

(d) host range, possibility of alteration;

(e) possibility of survival outside of human host;

(f) presence of vectors or means of dissemination;

(g) biological stability;

(h) antibiotic-resistance patterns;

(i) allergenicity;

(j) availability of appropriate therapies.

D. **Environmental considerations**

— factors affecting survival, multiplication and dissemination of the modified micro-organism in the environment;

— available techniques for detection, identification and monitoring of the modified micro-organism;

— available techniques for detecting transfer of the new genetic material to other organisms;

— known and predicted habitats of the modified micro-organism;

— description of ecosystems to which the micro-organism could be accidentally disseminated;

— anticipated mechanism and result of interaction between the modified micro-organism and the organisms or micro-organisms which might be exposed in case of release into the environment;

— known or predicted effects on plants and animals such as pathogenicity, infectivity, toxicity, virulence, vector of pathogen, allergenicity, colonization;

— known or predicted involvement in biogeochemical processes;

— availability of methods for decontamination of the area in case of release to the environment.

ANNEX IV

CONTAINMENT MEASURES FOR MICRO-ORGANISMS IN GROUP II

The containment measures for micro-organisms from Group II shall be chosen by the user from the categories below as appropriate to the micro-organism and the operation in question in order to ensure the protection of the public health of the general population and the environment.

Type B operations shall be considered in terms of their unit operations. The characteristics of each operation will dictate the physical containment to be used at that stage. This will allow selection and design of process, plant and operating procedures best fitted to assure adequate and safe containment. Two important factors to be considered when selecting the equipment needed to implement the containment are the risk of, and the effects consequent on, equipment failure. Engineering practice may require increasingly stringent standards to reduce the risk of failure as the consequence of that failure becomes less tolerable.

Specific containment measures for Type A operations shall be established taking into account the containment categories below and bearing in mind the specific circumstances of such operations.

Specifications	Containment Categories		
	1	2	3
1. Viable micro-organisms should be contained in a system which physically separates the process from the environment (closed system)	Yes	Yes	Yes
2. Exhaust gases from the closed system should be treated so as to:	Minimize release	Prevent release	Prevent release
3. Sample collection, addition of materials to a closed system and transfer of viable micro-organisms to another closed system, should be performed so as to:	Minimize release	Prevent release	Prevent release
4. Bulk culture fluids should not be removed from the closed system unless the viable micro-organisms have been:	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5. Seals should be designed so as to:	Minimize release	Prevent release	Prevent release
6. Closed systems should be located within a controlled area	Optional	Optional	Yes, and purpose-built
(a) Biohazard signs should be posted	Optional	Yes	Yes
(b) Access should be restricted to nominated personnel only	Optional	Yes	Yes, via airlock
(c) Personnel should wear protective clothing	Yes, work clothing	Yes	A complete change
(d) Decontamination and washing facilities should be provided for personnel	Yes	Yes	Yes
(e) Personnel should shower before leaving the controlled area	No	Optional	Yes
(f) Effluent from sinks and showers should be collected and inactivated before release	No	Optional	Yes

Specifications	Containment Categories		
	1	2	3
(g) The controlled area should be adequately ventilated to minimize air contamination	Optional	Optional	Yes
(h) The controlled areas should be maintained at an air pressure negative to atmosphere	No	Optional	Yes
(i) Input air and extract air to the controlled area should be HEPA filtered	No	Optional	Yes
(j) The controlled area should be designed to contain spillage of the entire contents of the closed system	Optional	Yes	Yes
(k) The controlled area should be sealable to permit fumigation	No	Optional	Yes
7. Effluent treatment before final discharge	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical means

ANNEX V

PART A

Information required for the notification referred to in Article 8:

— name of person(s) responsible for carrying out the contained use including those responsible for supervision, monitoring and safety and information on their training and qualifications;

— address of installation and grid reference; description of the sections of the installation;

— a description of the nature of the work which will be undertaken and in particular the classification of the micro-organism(s) to be used (Group I or Group II) and the likely scale of the operation;

— a summary of the risk assessment referred to in Article 6 (2).

PART B

Information required for the notification referred to in Article 9 (2):

— the date of submission of the notification referred to in Article 8;

— the parental micro-organism(s) used or, where applicable the host-vector system(s) used;

— the source(s) and the intended function(s) of the genetic material(s) involved in the manipulation(s);

— identity and characteristics of the genetically modified micro-organism;

— the purpose of the contained use including the expected results;

— the culture volumes to be used;

— a summary of the risk assessment referred to in Article 6 (2).

PART C

Information required for the notification referred to in Article 10 (1):

— the information required in Part B;

— description of the sections of the installation and the methods for handling the micro-organisms;

— description of the predominant meteorological conditions and of the potential sources of danger arising from the location of the installation;

— description of the protective and supervisory measures to be applied throughout the duration of the contained use;

— the containment category allocated specifying waste treatment provisions and the safety precautions to be adopted.

PART D

Information required for the notification referred to in Article 10 (2):

If it is not technically possible, or if it does not appear necessary to give the information specified below, the reasons shall be stated. The level of detail required in response to each subset of considerations is likely to vary according to the nature and the scale of the proposed contained use. In the case of information already submitted to the competent authority under the requirements of this Directive, reference can be made to this information by the user:

(a) the date of submission of the notification referred to in Article 8 and the name of the responsible person(s);

(b) information about the genetically modified micro-organism(s):

— the identity and characteristics of the genetically modified micro-organism(s),

— the purpose of the contained use or the nature of the product,

— the host-vector system to be used (where applicable),

— the culture volumes to be used,

— behaviour and characteristics of the micro-organism(s) in the case of changes in the conditions of containment or of release to the environment,

— overview of the potential hazards associated with the release of the micro-organism(s) to the environment,

— substances which are or may be produced in the course of the use of the micro-organism(s) other than the intended product;

(c) information about personnel:

— the maximum number of persons working in the installation and the number of persons who work directly with the micro-organism(s);

(d) information about the installation:

— the activity in which the micro-organism(s) is to be used,

— the technological processes used,

— a description of the sections of the installation,

— the predominant meteorological conditions, and specific hazards arising from the location of the installation;

(e) information about waste management:

— types, quantities, and potential hazards of wastes arising from the use of the micro-organism(s),

— waste management techniques used, including recovery of liquid or solid wastes and inactivation methods,

— ultimate form and destination of inactivated wastes;

(f) information about accident prevention and emergency response plans:

— the sources of hazards and conditions under which accidents might occur,

— the preventive measures applied such as safety equipment, alarm systems, containment methods and procedures and available resources,

— a description of information provided to workers,

— the information necessary for the competent authority to enable them to draw up or establish the necessary emergency response plans for use outside the installation in accordance with Article 14;

(g) a comprehensive assessment (referred to in Article 6 (2)) of the risks to human health and the environment which might arise from the proposed contained use;

(h) all other information required under Parts B and C if it is not already specified above.

COUNCIL DIRECTIVE

of 23 April 1990

on the deliberate release into the environment of genetically modified organisms

(90/220/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, under the Treaty, action by the Community relating to the environment should be based on the principle that preventive action should be taken;

Whereas living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby affecting other Member States; whereas the effects of such releases on the environment may be irreversible;

Whereas the protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release of genetically modified organisms (GMOs) into the environment;

Whereas disparity between the rules which are in effect or in preparation in the Member States concerning the deliberate release into the environment of GMOs may create unequal conditions of competition or barriers to trade in products containing such organisms, thus affecting the functioning of the common market; whereas it is therefore necessary to approximate the laws of the Member States in this respect;

Whereas measures for the approximation of the provisions of the Member States which have as their object the establishment and functioning of the internal market should, inasmuch as they concern health, safety, environmental and consumer protection, be based on a high level of protection throughout the Community;

Whereas it is necessary to ensure the safe development of industrial products utilizing GMOs;

Whereas this Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record;

Whereas it is necessary to establish harmonized procedures and criteria for the case-by-case evaluation of the potential risks arising from the deliberate release of GMOs into the environment;

Whereas a case-by-case environmental risk assessment should always be carried out prior to a release;

Whereas the deliberate release of GMOs at the research stage is in most cases a necessary step in the development of new products derived from, or containing, GMOs;

Whereas the introduction of GMOs into the environment should be carried out according to the 'step by step' principle; whereas this means that the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken;

Whereas no product containing, or consisting of, GMOs and intended for deliberate release shall be considered for placing on the market without it first having been subjected to satisfactory field testing at the research and development stage in ecosystems which could be affected by its use;

Whereas it is necessary to establish a Community authorization procedure for the placing on the market of products containing, or consisting of, GMOs where the intended use of the product involves the deliberate release of the organism(s) into the environment;

Whereas any person, before undertaking a deliberate release into the environment of a GMO, or the placing on the market of a product containing, or consisting of, GMOs, where the intended use of that product involves its deliberate release into the environment, shall submit a notification to the national competent authority;

Whereas that notification should contain a technical dossier of information including a full environmental risk assessment, appropriate safety and emergency response, and, in the case of products, precise instructions and conditions for use, and proposed labelling and packaging;

(1) OJ No C 198, 28. 7. 1988, p. 19 and OJ No C 246, 27. 9. 1989, p. 5.
(2) OJ No C 158, 26. 6. 1989, p. 225 and OJ No C 96, 17. 4. 1990.
(3) OJ No C 23, 30. 1. 1989, p. 45.

Whereas, after notification, no deliberate release of GMOs should be carried out unless the consent of the competent authority has been obtained;

Whereas the competent authority should give its consent only after it has been satisfied that the release will be safe for human health and the environment;

Whereas it may be considered appropriate in certain cases to consult the public on the deliberate release of GMOs into the environment;

Whereas it is appropriate for the Commission, in consultation with the Member States, to establish a procedure for the exchange of information on deliberate releases of GMOs notified under this Directive;

Whereas it is important to follow closely the development and use of GMOs; whereas a list should be published of all the products authorized under this Directive;

Whereas, when a product containing a GMO or a combination of GMOs is placed on the market, and where such a product has been properly authorized under this Directive, a Member State may not on grounds relating to matters covered by this Directive, prohibit, restrict or impede the deliberate release of the organism in that product on its territory where the conditions set out in the consent are respected; whereas a safeguard procedure should be provided in case of risk to human health or the environment;

Whereas the provisions of this Directive relating to placing on the market of products should not apply to products containing, or consisting of, GMOs covered by other Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive;

Whereas a Committee should be set up to assist the Commission on matters relating to the implementation of this Directive and to its adaptation to technical progress,

HAS ADOPTED THIS DIRECTIVE:

PART A

General provisions

Article 1

1. The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment:

— when carrying out the deliberate release of genetically modified organisms into the environment,

— when placing on the market products containing, or consisting of, genetically modified organisms intended for subsequent deliberate release into the environment.

2. This Directive shall not apply to the carriage of genetically modified organisms by rail, road, inland waterway, sea or air.

Article 2

For the purposes of this Directive:

(1) 'organism' is any biological entity capable of replication or of transferring genetic material;

(2) 'genetically modified organism (GMO)' means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Within the terms of this definition:

(i) genetic modification occurs at least through the use of the techniques listed in Annex I A Part 1;

(ii) the techniques listed in Annex I A Part 2 are not considered to result in genetic modification;

(3) 'deliberate release' means any intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment such as physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment;

(4) 'product' means a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market;

(5) 'placing on the market' means supplying or making available to third parties;

(6) 'notification' means the presentation of documents containing the requisite information to the competent authority of a Member State. The person making the presentation shall be referred to as 'the notifier';

(7) 'use' means the deliberate release of a product which has been placed on the market. The persons carrying out this use will be referred to as 'users';

(8) 'environmental risk assessment' means the evaluation of the risk to human health and the environment (which includes plants and animals) connected with the release of GMOs or products containing GMOs.

Article 3

This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.

Article 4

1. Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs.

2. Member States shall designate the competent authority or authorities responsible for carrying out the requirements of this Directive and its Annexes.

3. Member States shall ensure that the competent authority organizes inspections and other control measures as appropriate, to ensure compliance with this Directive.

PART B

Deliberate release of GMOs into the environment for research and development purposes or for any other purpose than for placing on the market

Article 5

Member States shall adopt the provisions necessary to ensure that:

(1) any person, before undertaking a deliberate release of a GMO or a combination of GMOs for the purpose of research and development, or for any other purpose than for placing on the market, must submit a notification to the competent authority referred to in Article 4 (2) of the Member State within whose territory the release is to take place;

(2) the notification shall include:

(a) a technical dossier supplying the information specified in Annex II necessary for evaluating the foreseeable risks, whether immediate or delayed, which the GMO or combination of GMOs may pose to human health or the environment, together with the methods used and the bibliographic reference to them and covering, in particular:

(i) general information including information on personnel and training,

(ii) information relating to the GMO(s),

(iii) information relating to the conditions of release and the receiving environment,

(iv) information on the interactions between the GMO(s) and the environment,

(v) information on monitoring, control, waste treatment and emergency response plans;

(b) a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged;

(3) the competent authority may accept that releases of a combination of GMOs on the same site or of the same GMO on different sites for the same purpose and within a limited period may be notified in a single notification;

(4) the notifier shall include in the notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by him either inside or outside the Community.

The notifier may also refer to data or results from notifications previously submitted by other notifiers, provided that the latter have given their agreement in writing;

(5) in the case of a subsequent release of the same GMO or combination of GMOs previously notified as part of the same research programme, the notifier shall be required to submit a new notification. In this case, the notifier may refer to data from previous notifications or results from previous releases;

(6) in the event of any modification of the deliberate release of GMOs or a combination of GMOs which could have consequences with regard to the risks for human health or the environment or if new information has become available on such risks, either while the notification is being examined by the competent authority or after that authority has given its written consent, the notifier shall immediately:

(a) revise the measures specified in the notification,

(b) inform the competent authority in advance of any modification or as soon as the new information is available,

(c) take the measures necessary to protect human health and the environment.

Article 6

1. On receipt and after acknowledgment of the notification the competent authority shall:

— examine it for compliance with this Directive,

— evaluate the risks posed by the release,

— record its conclusions in writing,

and, if necessary,

— carry out tests or inspections as may be necessary for control purposes.

2. The competent authority, having considered, where appropriate, any comments by other Member States made in accordance with Article 9, shall respond in writing to the notifier within 90 days of receipt of the notification by either:

(a) indicating that it is satisfied that the notification is in compliance with this Directive and that the release may proceed, or

(b) indicating that the release does not fulfil the conditions of this Directive and the notification is therefore rejected.

3. For the purpose of calculating the 90-day period referred to in paragraph 2, any periods of time during which the competent authority:

— is awaiting further information which it may have requested from the notifier,

or

— is carrying out a public inquiry or consultation in accordance with Article 7

shall not be taken into account.

4. The notifier may proceed with the release only when he has received the written consent of the competent authority, and in conformity with any conditions required in this consent.

5. If the competent authority considers that sufficient experience has been obtained of releases of certain GMOs, it may submit to the Commission a request for the application of simplified procedures for releases of such types of GMOs. The Commission shall, in accordance with the procedures laid down in Article 21, establish appropriate criteria and take a decision accordingly on each application. The criteria shall be based on safety to human health and the environment and on the evidence available on such safety.

6. If information becomes available subsequently to the competent authority which could have significant consequences for the risks posed by the release, the competent authority may require the notifier to modify the conditions of, suspend or terminate the deliberate release.

Article 7

Where a Member State considers it appropriate, it may provide that groups or the public shall be consulted on any aspect of the proposed deliberate release.

Article 8

After completion of a release, the notifier shall send to the competent authority the result of the release in respect of any risk to human health or the environment, with particular reference to any kind of product that the notifier intends to notify at a later stage.

Article 9

1. The Commission shall set up a system of exchange of the information contained in the notifications. The competent authorities shall send to the Commission, within 30 days of its receipt, a summary of each notification received. The format of this summary will be established by the Commission in accordance with the procedure laid down in Article 21.

2. The Commission shall immediately forward these summaries to the other Member States, which may, within 30 days, ask for further information or present observations through the Commission or directly.

3. The competent authorities shall inform the other Member States and the Commission of the final decisions taken in compliance with Article 6 (2).

PART C

Placing on the market of products containing GMOs

Article 10

1. Consent may only be given for the placing on the market of products containing, or consisting of, GMOs, provided that:

— written consent has been given to a notification under Part B or if a risk analysis has been carried out based on the elements outlined in that Part;

— the products comply with the relevant Community product legislation;

— the products comply with the requirements of this Part of this Directive, concerning the environmental risk assessment.

2. Articles 11 to 18 shall not apply to any products covered by Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive.

3. Not later than 12 months after notification of this Directive, the Commission, in accordance with the procedure laid down in Article 21, shall establish a list of Community legislation covering the products referred to in paragraph 2. This list will be re-examined periodically and, as necessary, revised in accordance with the said procedure.

Article 11

1. Before a GMO or a combination of GMOs are placed on the market as or in a product, the manufacturer or the importer to the Community shall submit a notification to the competent authority of the Member State where such a product is to be placed on the market for the first time. This notification shall contain:

— the information required in Annex II, extended as necessary to take into account the diversity of sites of use of the product, including information on data and results obtained from research and developmental releases concerning the ecosystems which could be affected by the use of the product and an assessent of any risks for human health and the environment related to the GMOs or a

combination of GMOs contained in the product, including information obtained from the research and development stage on the impact of the release on human health and the environment;

— the conditions for the placing on the market of the product, including specific conditions of use and handling and a proposal for labelling and packaging which should comprise at least the requirements laid down in Annex III.

If on the basis of the results of any release notified under Part B of this Directive, or on substantive, reasoned scientific grounds, a notifier considers that the placing on the market and use of a product do not pose a risk to human health and the environment, he may propose not to comply with one or more of the requirements of Annex III B.

2. The notifier shall include in this notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by the notifier either inside or outside the Community.

3. The notifier may also refer to data or results from notifications previously submitted by other notifiers, provided that the latter have given their agreement in writing.

4. Each new product which, containing or consisting of the same GMO or combination of GMOs, is intended for a different use, shall be notified separately.

5. The notifier may proceed with the release only when he has received the written consent of the competent authority in accordance with Article 13, and in conformity with any conditions, including reference to particular ecosystems/environments, required in that consent.

6. If new information has become available with regard to the risks of the product to human health or the environment, either before or after the written consent, the notifier shall immediately:

— revise the information and conditions specified in paragraph 1,

— inform the competent authority, and

— take the measures necessary to protect human health and the environment.

Article 12

1. On receipt and after acknowledgement of the notification referred to in Article 11, the competent authority shall examine it for compliance with this Directive, giving particular attention to the environmental risk assessment and the recommended precautions related to the safe use of the product.

2. At the latest 90 days after receipt of the notification, the competent authority shall either:

(a) forward the dossier to the Commission with a favourable opinion, or

(b) inform the notifier that the proposed release does not fulfil the conditions of this Directive and that it is therefore rejected.

3. In the case referred to in paragraph 2 (a), the dossier forwarded to the Commission shall include a summary of the notification together with a statement of the conditions under which the competent authority proposes to consent to the placing on the market of the product.

The format of this summary shall be established by the Commission in accordance with the procedure laid down in Article 21.

In particular where the competent authority has acceded to the request of the notifier, under the terms of the last subparagraph of Article 11 (1), not to comply with some of the requirements of Annex III B, it shall at the same time inform the Commission thereof.

4. If the competent authority receives additional information pursuant to Article 11 (6), it shall immediately inform the Commission and the other Member States.

5. For the purpose of calculating the 90-day period referred to in paragraph 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the notifier shall not be taken into account.

Article 13

1. On receipt of the dossier referred to in Article 12 (3), the Commission shall immediately forward it to the competent authorities of all Member States together with any other information it has collected pursuant to this Directive and advise the competent authority responsible for forwarding the document of the distribution date.

2. The competent authority, in the absence of any indication to the contrary from another Member State within 60 days following the distribution date referred to in paragraph 1, shall give its consent in writing to the notification so that the product can be placed on the market and shall inform the other Member States and the Commission thereof.

3. In cases where the competent authority of another Member State raises an objection — for which the reasons must be stated — and should it not be possible for the competent authorities concerned to reach an agreement within the period specified in paragraph 2, the Commission shall take a decision in accordance with the procedure laid down in Article 21.

4. Where the Commission has taken a favourable decision, the competent authority that received the original notification shall give consent in writing to the notification so that the product may be placed on the market and shall inform the other Member States and the Commission thereof.

5. Once a product has received a written consent, it may be used without further notification throughout the Community in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to.

6. Member States shall take all necessary measures to ensure that users comply with the conditions of use specified in the written consent.

Article 14

Member States shall take all necessary measures to ensure that products containing, or consisting of, GMOs will be placed on the market only if their labelling and packaging is that specified in the written consent referred to in Articles 12 and 13.

Article 15

Member States may not, on grounds relating to the notification and written consent of a deliberate release under this Directive, prohibit, restrict or impede the placing on the market of products containing, or consisting of, GMOs which comply with the requirements of this Directive.

Article 16

1. Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.

2. A decision shall be taken on the matter within three months in accordance with the procedure laid down in Article 21.

Article 17

The Commission shall publish in the *Official Journal of the European Communities* a list of all the products receiving final written consent under this Directive. For each product, the GMO or GMOs contained therein and the use or uses shall be clearly specified.

Article 18

1. Member States shall send to the Commission, at the end of each year, a brief factual report on the control of the use of all products placed on the market under this Directive.

2. The Commission shall send to the European Parliament and the Council, every three years, a report on the control by the Member States of the products placed on the market under this Directive.

3. When submitting this report for the first time, the Commission shall at the same time submit a specific report on the operation of this Part of this Directive including an assessment of all its implications.

PART D

Final provisions

Article 19

1. The Commission and the competent authorities shall not divulge to third parties any confidential information notified or exchanged under this Directive and shall protect intellectual property rights relating to the data received.

2. The notifier may indicate the information in the notification submitted under this Directive, the disclosure of which might harm his competitive position, that should therefore be treated as confidential. Verifiable justification must be given in such cases.

3. The competent authority shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decisions.

4. In no case may the following information when submitted according to Articles 5 or 11 be kept confidential:

— description of the GMO or GMOs, name and address of the notifier, purpose of the release and location of release;

— methods and plans for monitoring of the GMO or GMOs and for emergency response;

— the evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects.

5. If, for whatever reasons, the notifier withdraws the notification, the competent authorities and the Commission must respect the confidentiality of the information supplied.

Article 20

According to the procedure laid down in Article 21, the Commission shall adapt Annexes II and III to technical progress in particular by amending the notification requirements to take into account the potential hazard of the GMOs.

Article 21

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

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 22

1. Member States and the Commission shall meet regularly and exchange information on the experience acquired with regard to the prevention of risks related to the release of GMOs into the environment.

2. Every three years, Member States shall send the Commission a report on the measures taken to implement the provisions of this Directive, the first time being on 1 September 1992.

3. Every three years, the Commission shall publish a summary based on the reports referred to in paragraph 2, the first time being in 1993.

Article 23

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 23 October 1991.

2. Member States shall immediately inform the Commission of all laws, regulations and administrative provisions adopted in implementation of this Directive.

Article 24

This Directive is addressed to the Member States.

Done at Luxembourg, 23 April 1990.

For the Council

The President

A. REYNOLDS

ANNEX I A

TECHNIQUES REFERRED TO IN ARTICLE 2 (2)

PART 1

Techniques of genetic modification referred to in Article 2 (2) (i) are *inter alia:*

(1) recombinant DNA techniques using vector systems as previously covered by Council Recommendation 82/472/EEC (1);

(2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

(3) cell fusion (including protoplast fusion) or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART 2

Techniques referred to in Article 2 (2) (ii) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant DNA molecules or GMOs, are:

(1) *in vitro* fertilization,

(2) conjugation, transduction, transformation or any other natural process,

(3) polyploidy induction.

ANNEX I B

TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques of genetic modification to be excluded from this Directive, on condition that they do not involve the use of GMOs as recipient or parental organisms, are:

(1) mutagenesis,

(2) cell fusion (including protoplast fusion) of plant cells where the resulting organisms can also be produced by traditional breeding methods.

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(1) OJ NO L 213, 21. 7. 1982, p. 15.

ANNEX II

INFORMATION REQUIRED IN THE NOTIFICATION

The notifications for a deliberate release referred to in Article 5 and for placing on the market referred to in Article 11 must provide the information set out below.

Not all the points included will apply to every case. It is to be expected, therefore, that individual notifications will address only the particular subset of considerations that are appropriate to individual situations. In each case where it is not technically possible or it does not appear necessary to give the information, the reasons shall be stated.

The level of detail required in response to each subset of considerations is also likely to vary according to the nature and the scale of the proposed release.

The description of the methods used or the reference to standardized or internationally recognized methods shall also be mentioned in the dossier, together with the name of the body or bodies responsible for carrying out the studies.

I. GENERAL INFORMATION

A. Name and address of the notifier

B. Information on personnel and training

(1) Name of person(s) responsible for planning and carrying out the release including those responsible for supervision, monitoring and safety, in particular, name and qualifications of the responsible scientist;

(2) Information on training and qualifications of personnel involved in carrying out the release.

II. INFORMATION RELATING TO THE GMO

A. Characteristics of (a) the donor, (b) the recipient or (c) (where appropriate) parental organism(s):

1. scientific name;
2. taxonomy;
3. other names (usual name, strain name, cultivar name, etc.);
4. phenotypic and genetic markers;
5. degree of relatedness between donor and recipient or between parental organisms;
6. description of identification and detection techniques;
7. sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;
8. description of the geographic distribution and of the natural habitat of the organism including information on natural predators, preys, parasites and competitors, symbionts and hosts;
9. potential for genetic transfer and exchange with other organisms;
10. verification of the genetic stability of the organisms and factors affecting it;
11. pathological, ecological and physiological traits:
    (a) classification of hazard according to existing Community rules concerning the protection of human health and/or the environment;
    (b) generation time in natural ecosystems, sexual and asexual reproductive cycle;
    (c) information on survival, including seasonability and the ability to form survival structures e.g.: seeds, spores or sclerotia;
    (d) pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses). Ability to colonize other organisms;

(e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;

(f) involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.

12. Nature of indigenous vectors:

(a) sequence;

(b) frequency of mobilization;

(c) specificity;

(d) presence of genes which confer resistance.

13. History of previous genetic modifications.

B. Characteristics of the vector:

1. nature and source of the vector;

2. sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO;

3. frequency of mobilization of inserted vector and/or genetic transfer capabilities and methods of determination;

4. information on the degree to which the vector is limited to the DNA required to perform the intended function.

C. Characteristics of the modified organism:

1. Information relating to the genetic modification:

(a) methods used for the modification;

(b) methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;

(c) description of the insert and/or vector construction;

(d) purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;

(e) sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.

2. Information on the final GMO:

(a) description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;

(b) structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;

(c) stability of the organism in terms of genetic traits;

(d) rate and level of expression of the new genetic material. Method and sensitivity of measurement;

(e) activity of the expressed protein(s);

(f) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;

(g) sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;

(h) history of previous releases or uses of the GMO;

(i) health considerations:

(i) toxic or allergenic effects of the non-viable GMOs and/or their metabolic products;

(ii) product hazards;

(iii) comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

(iv) capacity for colonization;

(v) if the organism is pathogenic to humans who are immunocompetent

— diseases caused and mechanism of pathogenicity including invasiveness and virulence,

— communicability,

— infective dose,

— host range, possibility of alteration,

— possibility of survival outside of human host,

— presence of vectors or means of dissemination,

— biological stability,

— antibiotic-resistance patterns,

— allergenicity,

— availability of appropriate therapies.

III. INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT

A. **Information on the release:**

1. description of the proposed deliberate release, including the purpose(s) and foreseen products;
2. foreseen dates of the release and time planning of the experiment including frequency and duration of releases;
3. preparation of the site previous to the release;
4. size of the site;
5. method(s) to be used for the release;
6. quantities of GMOs to be released;
7. disturbance on the site (type and method of cultivation, mining, irrigation, or other activities);
8. worker protection measures taken during the release;
9. post-release treatment of the site;
10. techniques foreseen for elimination or inactivation of the GMOs at the end of the experiment;
11. information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems.

B. **Information on the environment (both on the site and in the wider environment):**

1. geographical location and grid reference of the site(s) (in case of notifications under Part C the site(s) of release will be the foreseen areas of use of the product);
2. physical or biological proximity to humans and other significant biota;
3. proximity to significant biotopes or protected areas;
4. size of local population;
5. economic activities of local populations which are based on the natural resources of the area;
6. distance to closest areas protected for drinking water and/or environmental purpose;
7. climatic characteristics of the region(s) likely to be affected;
8. geographical, geological and pedological characteristics;
9. flora and fauna, including crops, livestock and migratory species;
10. description of target and non-target ecosystems likely to be affected;
11. a comparison of the natural habitat of the recipient organism with the proposed site(s) of release;
12. any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOs AND THE ENVIRONMENT

A. **Characteristics affecting survival, multiplication and dissemination:**

1. biological features which affect survival, multiplication and dispersal;
2. known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, etc.);
3. sensitivity to specific agents.

B. **Interactions with the environment:**

1. predicted habitat of the GMOs;
2. studies of the behaviour and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses;
3. genetic transfer capability:
   (a) post-release transfer of genetic material from GMOs into organisms in affected ecosystems;
   (b) post-release transfer of genetic material from indigenous organisms to the GMOs;
4. likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the modified organism;
5. measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimize dispersal of genetic material. Methods to verify genetic stability;
6. routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.;
7. description of ecosystems to which the GMOs could be disseminated.

C. **Potential environmental impact:**

1. potential for excessive population increase in the environment;
2. competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s);
3. identification and description of the target organisms;
4. anticipated mechanism and result of interaction between the released GMOs and the target organism;
5. identification and description of non-target organisms which may be affected unwittingly;
6. likelihood of post-release shifts in biological interactions or in host range;
7. known or predicted effects on non-target organisms in the environment, impact on population levels of competitors: preys, hosts, symbionts, predators, parasites and pathogens;
8. known or predicted involvement in biogeochemical processes;
9. other potentially significant interactions with the environment.

V. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

A. **Monitoring techniques:**

1. methods for tracing the GMOs, and for monitoring their effects;
2. specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques;
3. techniques for detecting transfer of the donated genetic material to other organisms;
4. duration and frequency of the monitoring.

B. **Control of the release:**

1. methods and procedures to avoid and/or minimize the spread of the GMOs beyond the site of release or the designated area for use;
2. methods and procedures to protect the site from intrusion by unauthorized individuals;
3. methods and procedures to prevent other organisms from entering the site.

C. **Waste treatment:**

1. type of waste generated;
2. expected amount of waste;
3. possible risks;
4. description of treatment envisaged.

D. **Emergency response plans:**

1. methods and procedures for controlling the GMOs in case of unexpected spread;
2. methods for decontamination of the areas affected, e.g. eradication of the GMOs;
3. methods for disposal or sanitation of plants, animals, soils, etc. that were exposed during or after the spread;
4. methods for the isolation of the area affected by the spread;
5. plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

ANNEX III

ADDITIONAL INFORMATION REQUIRED IN THE CASE OF NOTIFICATION FOR PLACING ON THE MARKET

A. The following information shall be provided in the notification for placing on the market of products, in addition to that of Annex II:

1. name of the product and names of GMOs contained therein;
2. name of the manufacturer or distributor and his address in the Community;
3. specificity of the product, exact conditions of use including, when appropriate, the type of environment and/or the geographical area(s) of the Community for which the product is suited;
4. type of expected use: industry, agriculture and skilled trades, consumer use by public at large.

B. The following information shall be provided, when relevant, in addition to that of point A, in accordance with Article 11 of this Directive:

1. measures to take in case of unintended release or misuse;
2. specific instructions or recommendations for storage and handling;
3. estimated production in and/or imports to the Community;
4. proposed packaging. This must be appropriate so as to avoid unintended release of the GMOs during storage, or at a later stage;
5. proposed labelling. This must include, at least in summarized form, the information referred to in points A. 1, A. 2, A. 3, B. 1 and B. 2.

COUNCIL DECISION

of 23 April 1990

concerning the framework programme of Community activities in the field of research and technological development (1990 to 1994)

(90/221/Euratom, EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 130q (1) thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 7 thereof,

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

Having regard to the opinion of the European Parliament (2),

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

Whereas the Single European Act incorporated a Title VI (Articles 130f to 130q) into the EEC Treaty; whereas that Title constitutes a new legal basis for Community activities in the field of research and technological development; whereas, in particular, Article 130f lays down that the Community's aim is to strengthen the scientific and technological basis of European industry and to encourage it to become more competitive at international level;

Whereas it is necessary for the Community to encourage enterprises, including small and medium-sized undertakings, research centres and universities in their research and technological development activities and, in order to achieve that, to support their efforts to cooperate with one another by appropriate measures;

Whereas it is recognized that small and medium-sized undertakings are able to make a significant contribution to the innovative process and should play a substantial role in the implementation of Community research and technological development activities, thereby contributing to the improvement of industrial competitiveness on a broader basis; whereas, therefore, particular attention should be paid to the specific needs of these undertakings in order to encourage their access to information, their effective participation in Community programmes and their ability to exploit the results of Community research;

(1) OJ NO C 243, 23. 9. 1989, p. 4.
(2) OJ NO C 15, 22. 1. 1990, p. 356.
(3) OJ NO C 56, 7. 3. 1990, p. 34.

Whereas under Article 130i all the Community activities referred to in Article 130g should be set out in a multiannual framework programme;

Whereas, following an initial framework programme for the period 1984 to 1987, a second framework programme for the period 1987 to 1991 was adopted by Decision 87/516/Euratom, EEC (4) amended by Decision 88/193/EEC, Euratom (5), and is in the process of being implemented; whereas it should be possible to continue implementing it, for specific programmes which have not yet been adopted, even after adoption of the third framework programme for the period 1990 to 1994;

Whereas the Commission submitted a communication on 'a framework for Community research and technological development actions in the 1990s' on 13 June 1989;

Whereas, in addition, pursuant to Article 4 of Decision 87/516/Euratom, EEC, the Commission has examined and assessed progress in carrying out the second framework programme, in particular through an evaluation report prepared by a group of independent experts;

Whereas, in view of the rapid pace of technological development, new economic challenges which the Community must meet, the increased level of global competition and the need to keep in view the horizon beyond 1992, Community activities in the field of research and technological development must be intensified and augmented; whereas, in the light of these factors, it has been judged appropriate to adopt a new framework programme for the period 1990 to 1994 developing out of the current framework programme 1987 to 1991;

Whereas the Community's activities must be based on the principle of subsidiarity, and whereas the Community's activities in the field of research and technological development must thus provide added value in relation to activities carried out at national and other levels;

Whereas efforts should be focused on a limited number of activities corresponding to the strategic objectives laid down in the framework programme;

(4) OJ NO L 302, 24. 10. 1982, p. 1.
(5) OJ NO L 89, 6. 4. 1988, p. 35.

Whereas it is necessary to promote the overall harmonious development of the Community with a view to strengthening its economic and social cohesion; whereas it is intended that the implementation of common policies of the Community and its strategy for research and technological development shall contribute to this objective; whereas a Community framework programme should play its part, along with other Community instruments, in contributing to strengthening scientific and technological infrastructure and potential throughout all parts of the Community;

Whereas the process of technological progress requires a continuum of interlinked activities, ranging from basic research through to the demonstration of the applications of new technologies; whereas, however, the pre-competitive aspect must remain central and still take priority in Community research and technological development;

Whereas the prenormative dimension referred to in Article 130f of the Treaty could enable Community research and technological development activities to guarantee the scientific and technical basis necessary to establish adequate norms and standards; whereas such an approach will help make it easier for the Community to meet the increased responsibilities linked with completion of the single market, in other areas such as the environment, safety and health;

Whereas the Joint Research Centre is called on to contribute to the implementation of the framework programme particularly in those fields in which it can offer an impartial and independent expert opinion for the benefit of all Community policies;

Whereas the dissemination and exploitation of the results of research and technological development activities are essential elements in the innovative process, in particular for small and medium-sized undertakings; whereas, for this reason, each specific programme must specify the procedures for disseminating results, and provision should be made for centralized action to disseminate and exploit the results of research;

Whereas a new initiative should be launched to improve the mobility and training of young researchers at postgraduate level, particularly relying on networks of laboratories and research teams, both public and private, in Member States, throughout the whole Community;

Whereas the framework programme is to be implemented through specific programmes and may also be implemented through supplementary programmes within the meaning of Article 130l, participation within the meaning of Article 130m and cooperation with third countries or international organizations within the meaning of Article 130n or may take the form of joint undertakings or other structures within the meaning of Article 130o of the EEC Treaty;

Whereas a complementary relationship should be promoted between Community activities and Eureka projects which fit in with the extension of the Community's research and technological development strategy, by the choice of appropriate instruments, in accordance with Articles 130m and n of the EEC Treaty;

Whereas the Community is ready to cooperate, on a mutually advantageous basis, with third countries, particularly those which have concluded framework agreements with the Communities;

Whereas European Cooperation in the field of scientific and technical research (COST) activities are making an increased contribution to the implementation of the framework programme and playing a specific and complementary role by encouraging scientific and technical cooperation between the Community and the members of COST by means of research projects of a multilateral character;

Whereas it is necessary to make an estimate of the Community financial means necessary for the realization of the research and development activities envisaged, in accordance with Article 130i (1) of the EEC Treaty; whereas this amount is compatible with the financial perspective included in the Interinstitutional Agreement of 29 June 1988 for the years 1990 to 1992;

Whereas as regards the implementation of the framework programme in 1993 and 1994 provision should be made for the amount deemed necessary and the continuity of research activities should be ensured;

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

Whereas the Scientific and Technical Committee referred to in Article 7 of the EAEC Treaty has been consulted by the Commission and has delivered its opinion,

HAS DECIDED AS FOLLOWS:

Article 1

1. This framework programme for Community activities in the field of research and technological development, hereinafter referred to as the 'third framework programme', shall cover the period 1990 to 1994. The Decisions adopted in implementation of Decision 87/516/Euratom, EEC, concerning the framework programme for 1987 to 1991 shall not be affected by this Decision. The remaining Decisions necessary to complete the implementation of Decision 87/516/Euratom, EEC, may be adopted.

2. The third framework programme shall provide for the carrying out of the following activities:

— enabling technologies:

1. information and communications technologies;
2. industrial and materials technologies.

— management of natural resources:

3. environment;

4. life sciences and technologies;

5. energy.

— management of intellectual resources:

6. human capital and mobility.

3. Without prejudice to the amount of ECU 3 125 million deemed necessary in respect of the framework programme for 1987 to 1991, which it will be possible to enter in the budget from 1990 onwards, the amount deemed necessary for Community financial participation in the entire programme shall be ECU 5 700 million, of which ECU 2 500 million are deemed to be necessary during 1990, 1991 and 1992 and ECU 3 200 million during 1993 and 1994.

4. The latter amount shall be intended for the financing in 1993 and 1994 of activities begun in the period 1990 to 1992. If this amount is covered by any financial perspective fixed for 1993 and 1994, it shall be deemed to be confirmed. In any other circumstances, the Council should as soon as possible take, in accordance with Article 130q (1), the decisions deemed necessary to ensure the continuity of the present framework programme.

5. The breakdown of the amount deemed necessary for the period 1990 to 1994 between the six activities referred to in paragraph 2 is set out in Annex I.

6. The activities referred to in paragraph 2 and their scientific and technical objectives are described in Annex II.

7. The selection criteria to be applied in the implementation of the framework programme are laid down in Annex III.

Article 2

1. The third framework programme shall be implemented through specific programmes in accordance with Articles 130k and 130p of the EEC Treaty. For activities covered by the EAEC Treaty, programmes shall be adopted in accordance with Article 7 of the said Treaty. Each programme shall fall within one of the activities referred to in Article 1 (2).

2. This implementation may also give rise, as necessary, to supplementary programmes within the meaning of Article 130l, to participation within the meaning of Article 130m, to cooperation within the meaning of Article 130n and to joint undertakings or any other structure within the meaning of Article 130o of the EEC Treaty. In such cases the decision shall be taken by the Council pursuant to the rules of the Treaty.

3. If a decision is taken in implementation of Article 1 (4), the various specific programmes or other decisions shall be adjusted to take account of such decision.

4. Each specific programme shall determine its precise objectives and make provision for an evaluation of the results achieved as compared with those objectives and with the criteria in Annex III, which include that of contributing to the economic and social cohesion of the Community.

Article 3

The detailed rules for financial participation by the Communities in the third framework programme as a whole shall be those provided for by the Financial Regulation applicable to the general budget of the European Communities.

The rates of financial participation by the Community are set out in Annex IV.

Article 4

Measures to disseminate the knowledge gained from and to exploit the results of the specific programmes and the supplementary programmes, as described in Annex II, shall be implemented, on the one hand, through the specific and supplementary programmes and, on the other, by means of a centralized action.

The amount deemed necessary for the abovementioned centralized action is ECU 57 million, as indicated in Annex I.

The detailed arrangements for the dissemination and exploitation of the knowledge gained, in particular the definition and the implementation of the centralized action, shall be the subject of a Council Decision.

Article 5

During the third year of execution of the third framework programme, the Commission shall assess its progress by reference to the criteria set out in Annex III. It shall examine in particular whether the objectives, priorities and activities envisaged and financial resources are still appropriate to the changing situation. It shall also make an evaluation of all the specific programmes implemented under Decision 87/516/Euratom, EEC. It shall communicate the findings of this examination and evaluation to the Council together with its comments.

After the Council has examined this communication, the Commission shall submit to it the necessary proposals for decisions.

When implementation of the third framework programme has been completed, the Commission shall make a new evaluation of that programme.

Done at Luxembourg, 23 April 1990.

For the Council

The President

A. REYNOLDS

ANNEX I

BREAKDOWN OF THE AMOUNTS DEEMED NECESSARY TO IMPLEMENT THE VARIOUS ACTIVITIES ENVISAGED

(in millions of ecus)

	1990—92	1993—94	Total
I. ENABLING TECHNOLOGIES			
1. Information and communications technologies	**974**	**1 247**	**2 221**
— Information technologies	1 352		
— Communications technologies	489		
— Development of telematics systems of general interest	380		
2. Industrial and materials technologies	**390**	**498**	**888**
— Industrial and materials technologies	748		
— Measurement and testing	140		
II. MANAGEMENT OF NATURAL RESOURCES			
3. Environment	**227**	**291**	**518**
— Environment	414		
— Marine sciences and technologies	104		
4. Life sciences and technologies	**325**	**416**	**741**
— Biotechnology	164		
— Agricultural and agro-industrial research (1)	333		
— Biomedical and health research	133		
— Life sciences and technologies for developing countries	111		
5. Energy	**357**	**457**	**814**
— Non-nuclear energies	157		
— Nuclear fission safety	199		
— Controlled nuclear fusion	458		
III. MANAGEMENT OF INTELLECTUAL RESOURCES			
6. Human capital and mobility	**227**	**291**	**518**
— Human capital and mobility	518		
TOTAL	2 500	3 200	5 700 (2)(3)

(1) Including fisheries.
(2) Including ECU 57 million for the centralized action of dissemination and exploitation provided for in Article 4, drawn proportionally from each activity.
(3) Including ECU 180 million for 1990—92 and ECU 370 million for 1993—94 for the Joint Research Centre.

ANNEX II

THE ACTIVITIES

The third framework programme of research and technological development (1990—94) defines objectives for giving an innovatory thrust to Community action during those five years. The specific programmes of the second framework programme (1987—91) are retained. The third framework programme will be able to bring to them the necessary elements of continuity.

The selection of the broad outlines of the third framework programme meets six major concerns:

— improving industrial competitiveness whilst maintaining the pre-competitive nature of Community activities;

— meeting the challenges linked to the attainment of the large market as regards norms and standards by strengthening prenormative research;

— modifying industrial operators' attitudes in the direction of further transnational initiatives;

— introducing a European dimension into the training of scientific research and technological development staff;

— increasing economic and social cohesion whilst ensuring the scientific and technical excellence of research projects;

— taking into account environmental protection and the quality of life.

The choice of scientific and technical objectives rests *inter alia* on the principle of Community added value and subsidiarity. In this sense, the criteria laid down for the previous framework programme and set out in Annex III take on an added significance; they will be taken into account in the evaluation of the different activities.

There will be greater consultation of representative scientific, technical and industrial bodies in the Community.

In industrial programmes, the emphasis will be on pre-competitive research and technological development. The main objective will be to contribute to strengthening the technological bases for the development of standards in order to encourage the attainment of the single large market, thus making it possible for industry to invest in the design of products on the basis of common standards. Transfer of technology in order to encourage the use of new technologies will assume particular importance and will include certain demonstration projects with particular reference to use of such standards. There will be no financing of product development.

The principal instrument of the specific programmes remains the shared-cost action, without ruling out the possibility of adjusted rates of support. In those cases where coordination of existing research activities at national level is the predominant aspect, concerted action will be used. The other methods of implementation provided for in the Treaty may be used, in particular to establish or strengthen links with long-term Eureka projects meeting the criteria for Community action.

The Joint Research Centre is to participate in the implementation of the framework programme in those fields where it has the necessary competence. These are *inter alia* industrial and materials technologies, research with a prenormative character, nuclear safety (fission and fusion), technological forecasting, the environment and industrial risks.

The research, development and innovative capacities of small and medium-sized undertakings, higher education establishments and research centres will be given sustained attention and their activities in partnership will be encouraged. Particular attention will be given to promoting the access of small and medium-sized undertakings to Community programmes.

Emphasis will also be placed on the various courses of action on fundamental research geared to any area where it might become necessary.

The Council will define the detailed arrangements for the dissemination of knowledge resulting from the specific programmes and other arrangements for implementing the framework programme. Within this legal framework, dissemination activities will be coherent and coordinated, which presupposes on the one hand a central level of management and on the other freedom of action in specific programmes to organize a level of specialized dissemination. In both cases, such activities may be carried out in particular through publications or by computerized means according to common standards and protocols.

The activity of dissemination will also cover information on Community programmes and actions to provide easier access to information for small and medium-sized undertakings and private and public research laboratories. To this end, encouragement will be given to the creation or extension of the activities of national and regional relay centres for the dissemination and exploitation of results.

As far as the exploitation of results is concerned, although it is clear that in the first place it is the responsibility of undertakings and laboratories, in certain cases it requires Community action, coordinated with the operators concerned and the competent public or private organizations in particular at national or regional level (including *inter alia* the above relay centres), in order to protect certain results and facilitate and guarantee the best possible innovation transfer.

Both for the dissemination of knowledge and for the exploitation of results, it is necessary to specify or define the rules concerning intellectual and industrial property and the exploitation of the results within the Community and to observe them.

In addition to the evaluation activities involved in the various programmes, work on the methodology of evaluation, forecasting and strategic analysis will also continue unabated in cooperation with the Member States with a view to improving the effectiveness of Community research.

In strict accordance with the guiding character given to the framework programme by the Treaty, the following paragraphs make reference to the strategic elements of the 1990—94 framework programme.

I. ENABLING TECHNOLOGIES

1. Information and communications technologies

The development of the relationship between information and communications technologies, the increased requirements of users regarding standardized systems and trans-European services networks to assist in unifying the European area and the strengthening of scientific and technological bases lead work on information and communications technologies to be directed in three main ways. An essential aim is to achieve open standards making it possible to improve the integration of advanced systems into the networks. In all the areas concerned, the active participation of users and small and medium-sized undertakings and the transfer of technology to their advantage will be encouraged.

A. *Information technology*

Whilst ensuring that all the work relating to information technologies remains focused in the pre-competitive area, the emphasis will be placed, on the one hand, on demonstration activities for the preparation and validation of standards and for the integration of technologies and, on the other, on basic research, in particular in sectors which have the potential to make a substantial impact on industrial innovation, such as the cognitive sciences. In addition, activities on topics dealt with in the Esprit programme will be oriented towards the new generations of technologies. In a general sense, the balances between the various basic areas of technology defined in Esprit II (including those for microelectronics) will be respected.

The various activities envisaged may be grouped round four large fundamental topics which contain elements of continuity but also exhibit new facets in comparison with earlier research.

(a) Microelectronics

The objective is to contribute, by means of pre-competitive research and technological development work, to the strengthening of the European technological base in respect of semiconductors on which to base a European manufacturing capability for advanced products and the technologies for component processing. This work will also concern application-specific integrated circuits (ASIC), multi-function circuits, very fast circuits, opto-electronics, advanced power circuits (smart power), new equipment and materials for integrated circuits and, in conjunction with other initiatives in the Community such as Jessi, the technologies linked to submicron silicon.

Research into and development of advanced and standardized computer-aided design tools for integrated circuits will also be pursued, particular attention being given to users' needs.

These actions will be organized in such a way as to link users and producers and encourage and ensure broad participation by operators in the Community as a whole, for the benefit of all.

(b) Information processing systems and software

The rapid development of this sector leads research to be directed towards parallel architectures, knowledge-based systems, work stations, hosts and distributed and real time systems. The tools and methods necessary to increase the productivity of the software and the integration of the systems will continue to be developed.

Emphasis will be placed on the portability of the software, re-usability and design of standardized modules and on prenormative research. Attention will also be given to seeing that European industry, in particular small and medium-sized undertakings, can adopt standardized software on a large scale and use the best practices in the area of programming tools, methods and environments, taking account of national activities in this area.

(c) Advanced office technology systems and peripherals

The main objective will be to use European technological competence to construct improved forms of architecture, software packages and other system components capable of adding to the value of devices and systems, in particular those based on standards.

The two main themes are research and development concerning the use of software engineering for the development of selective applications based on open standards and the integration of sophisticated information systems and interfaces. Among the fields concerned may be cited information systems adapted to mobile terminals, cooperation work (groupware), house automation and intelligent buildings and integrated data processing systems for business.

In this context, peripherals take on an added importance. The objective of research and development work is to reinforce the scientific and technological bases for new generations of peripherals which are reliable, cheap and capable of being produced in large quantities, without going as far as product development. This requires the use not only of basic technologies at the best state-of-the-art level, but also of new generic methods of manufacture. The action will have to lead, for instance, to new in-out arrangements and storage systems.

(d) Computer-integrated manufacturing and application of information technology to industrial engineering

The objective is to provide, by means of pre-competitive research and technological development work, the bases for open, multisite and multi-vendor systems. The work will cover planning and scheduling systems, production control, computer-assisted engineering systems, robotics and quality-guarantee technologies. The areas concerned are those of discontinuous, continuous and batch manufacture, flexible assembly and mass production. Technology transfer activities will comprise some demonstration projects in which information technologies occupy an important position and which may be launched in real industrial environments enabling standards to be validated and their use to be promoted. These activities will be carried out in close coordination with those under heading 2.

This action will contribute to better integration in advanced systems of design and computer-assisted production of the needs voiced by industrialists including problems of work integration and organization and job evaluation.

B. *Communications technologies*

The principal objective is to enable the integrated broadband network to take on the emerging new services, constructed on 'open' standards, and to make the use of integrated services both flexible and cheaper.

Parallel to the continued development of the integrated broadband network and the strengthening of the research effort on optical communications and techniques of synchronic/asynchronic switching, the new activities will be directed towards the development of intelligent, reliable and secure networks and new value-added services that are both profitable and adapted to the developing needs of users. These actions include a Community R & D effort of the prenormative type in order to guarantee the interoperability of the systems on the basis of common standards and protocols.

Particular attention will be given to the growing demand for mobile telephony services and the integration of these services into networks.

The following actions are planned:

— **Development of intelligent networks,** using new techniques of information transfer, optical communications and possibly artificial intelligence. The objective is to enable second-generation systems to exploit foreseeable progress in data processing. This requires research and

technological development work in the fields of standardization and interconnection protocols. This work should take into account the development of a new European regulatory environment on open architecture (ONP — Open Network Provision).

— **Mobile communications.** The objective is to contribute to definition of the standards necessary for the third-generation system which should appear on a time-scale of 1996 and beyond and permit the exploitation of new hyperfrequencies in mobile telecommunications services.

— **Image communication:** building on numerical image transfer (including high-definition television — HDTV), research efforts are needed into processing, storage and display to integrate image into multimedia communications and to ensure the development of allied protocols and coders-decoders.

— **Service engineering:** work of a prenormative type on architectures and software, realized on basic teleservices and on improved value-added services, with particular attention to their ease of use by small and medium-sized undertakings and preparing the scientific and technological bases for development of standards both for systems and for telecommunications services.

— **Experiments in advanced communications.** It will be necessary to identify the characteristics and functions of certain advanced model services. These experiments of a generic kind, in real conditions, will contribute to developing interconnection standards and to verifying the feasibility of integrated communication systems so as to limit the dangers when they are introduced later.

— **Security of information.** The objective is to contribute to the development of technologies which can guarantee effective and practical security meeting the requirements of interconnected or integrated communication services used by economic operators and by the general public. Priority research and technological development work is required to contribute to the definition of international standards and verification technologies.

C. *Development of telematic systems in areas of general interest*

The general objective consists, by means of prenormative research and a limited number of experimental development activities concerning the validation of common functional specifications, in ensuring the interoperability of systems, peripherals and telematic networks at trans-European level. Special attention will be given to considerations of quality, reliability, security and ease of use of services, and to economies of scale and the abolition of barriers to information exchange.

The work will be carried out in areas corresponding both to requirements resulting from the implementation of the large European market and the new increased requirements of a social and economic nature which can both benefit from the use of new telematic resources.

The realization of the large internal market is setting new requirements in the field of services and information exchange. In relations between public administrations, new requirements are being expressed, for instance, in the areas of emergency services, justice, the social services, statistics, customs and the environment. Sectors of general concern are dominated by questions of transport, health, problems relating to the handicapped and aged, problems of training, problems of links between libraries and access to rural areas.

To meet these requirements, beyond the efforts being undertaken within regional or national contexts, an additional Community effort is also needed in research and technological development.

More specifically, some of these sectors have already been explored in the course of exploratory activities (AIM, Delta, Drive) or preliminary activities (investigation of needs in rural areas and libraries). The planned research and technological development actions will be based on the experience and results obtained from these exploratory actions. Endeavours will be made to achieve their continuity so as not to lose the advantage of the community of interest created.

It will only be possible to develop such projects fully outside the framework programme: the setting-up and exploitation of networks and services are not covered by this work.

In each of the above two areas, making services easier to use will require a sustained effort in language research and engineering. Following work already done as part of the Eurotra programme, it is now necessary to encourage the development of operational systems linked to information and communications systems.

All these actions will involve information and communications industries, telecommunications operators, providers of telecommunications services and pioneer users of advanced communications. In the case of telematic services, the trans-European dimension will be even more necessary for success than elsewhere.

2. **Industrial and materials technologies**

The objective is to contribute to the rejuvenation of European manufacturing industry by strengthening its scientific base through research and development work. With that in mind it is important to encourage:

— basic technical research;

— integration of new technologies by user industries;

— acquisition of the scientific and technical knowledge needed in order to establish standards and codes of good practice facilitating the transfer of such technologies;

— harmonization of methods of measurement and testing.

The advanced technologies required cover the whole life-cycle of materials and aim at reducing the 'design to product' lead time and improving manufacturing processes. In selecting actions to be implemented, account will be taken of the experience acquired through current programmes and pilot projects (Brite-Euram, Raw Materials, Recycling and BCR).

These technological developments will integrate considerations of future market requirements and more severe constraints as regards the environment and working conditions, while at the same time enabling improvements to be made in the competitiveness of European producers and users.

The more it can be guaranteed that technologies will have a human dimension, the more the quality of work and consequently the quality of production will increase. Work will therefore cover research and development concerning the working environment and continuous adaptation of the skills of workers to technological change. New methods of management and organization will be sought in order to ensure a smooth relationship between technology and the working world.

Work carried out in any of the three areas described below will be linked to the others and consequently not performed in isolation, but under a systematic approach. Research on new materials will be closely linked to research on the design and manufacturing processes needed to make economic use of the materials and prenormative research allowing the incorporation of such materials into products and ensuring environmental acceptability.

The research work proposed will help to consolidate and further technological developments within the Community and make more effective use of resources. A particular effort will be made to help small and medium-sized undertakings become more involved in transnational research, develop links with other undertakings and universities and manage their technical resources better.

Research on measurements and testing is necessary to the application of harmonization of quality standards and testing methods and the acceptance of results throughout the Community. Greater collaboration between laboratories will improve the quality of results and their acceptability, as called for by the completion of the single market.

This approach concerns both the following areas of activity and their interfaces:

A. *Materials — Raw materials*

The objective is to contribute to improving the performances of materials at a cost which permits competitive industrial exploitation over a broad range of applications not restricted to a few high-performance items. The aim will be to promote an integrated approach to the whole life-cycle of materials, including recycling.

The activities in question will concern both research on advanced materials for key applications, such as ceramic composites and metallic matrices, which may have important spin-off effects in other areas, and research on traditional materials of broader application, such as are used in the construction industry where improvements to the materials life-cycle are needed.

Emphasis will be placed on research enabling innovative uses of materials, metals and industrial minerals, and on their production and processing, including exploration, recovery and recycling.

There will also be strong encouragement to undertake basic research and exploit emerging and rapidly-developing technologies.

Particular attention will be paid to research into new materials to improve understanding of their structures and properties, including the production cycle.

B. *Design and manufacturing*

The objective is to reduce the 'design to product' lead time and to improve the means, processes and management of design and manufacturing operations, on the basis of the state of the generic technologies concerned.

Emphasis will be placed, *inter alia,* on quality, reliability, the control of products and processes, and on the research and technological development work needed for the adaptation of computer-aided design and manufacturing techniques, especially for small and medium-sized undertakings. Care will be taken to ensure close coordination of this activity with the generic aspects of such design and manufacturing techniques covered by heading 1.

The development of the technologies necessary for the modernization of European industry requires a basic research effort, in particular in the areas of physics and chemistry. Similarly, recourse will be had at the same time to generic disciplines (such as mathematical modelling, acoustics, fluid dynamics, process engineering, etc.) and new technological developments (concerning, for example, surface treatment, miniaturization, optomatronics, etc.).

C. *Measurement and testing*

The objective is to lead, by means of improved harmonization of methods of testing, measuring and analysis, to the elimination of certain obstacles to trade in the large internal market.

To that end, transnational actions will be undertaken in four main fields: establishing the scientific and technical bases for Community regulations and directives concerning measurements (including exploitation of research results concerning instrumentation), testing and analysis; the resolution of such sectoral testing problems as might arise when an international approach to certification and testing is adopted and implemented; work arising out of a coordinated approach to the provision of measuring standards adopted henceforward in the Community; and support for the development of new methods of measurement.

The drawing up and implementation of standards and codes of good practice, which are necessary to meet the requirements of the market and which require prenormative research and development work, will be guaranteed by means of the research programmes concerned and are covered by other lines of activity.

In carrying out the research outlined above, flexibility of means of action will be particularly important. Two notable means of implementing these proposals will be:

— Technological stimulus and cooperative research action to extend current initiatives, an open arrangement, without any constraints of theme or timetable, will be set up to support particularly innovative technological projects which, at any given time, could not be included in the other actions. This will help in particular to solve technical problems common to groups of small and medium-sized undertakings without research facilities of their own. This activity is defined in relation to the other sections of the programme as meaning that as a general rule only small and medium-sized undertakings can be considered, in conjunction where appropriate with research centres, with a view to increasing their involvement in Community research programmes.

— While maintaining the generic approach followed under this heading, selected integrated projects will be considered in appropriate fields where a range of generic technologies need to be brought together with a view to providing users with a definition of operational specifications. These projects will have specific targeted objectives, bringing suppliers and users together in a systematic approach and at the same time facilitating the participation of small and medium-sized undertakings. Product development and commercialization will be a matter for the competent industries.

  In view of the needs created by the setting up of the large internal market, the fields to be considered here would include, for instance, transport (which may be the subject of integrated activities concerning, for example, the aeronautical industry — after evaluation, the motor industry and the 'clean car'). The logistical aspects of harmonization and standardization of means of transport will also be given special attention in conjunction with the activities under heading 1. Other fields will be likely to benefit from an integrated approach.

In general, all these actions will have to contribute to the emergence of European small and medium-sized undertakings, in particular by encouraging their integration in the technological networks developed at that time.

The Joint Research Centre will contribute to these activities via work on advanced materials which gives priority to the prenormative aspect, the preparation of nuclear and non-nuclear reference materials, the acquisition of reference data and the validation of certain reference techniques.

II. MANAGEMENT OF NATURAL RESOURCES

3. Environment

Here the purpose is to develop the scientific knowledge and technical know-how the Community needs in particular to carry out its role concerning the environment, as spelt out in Title VII of the EEC Treaty.

In this sector, the research activities are directed towards an understanding of the fundamental mechanisms of the environment, identification of pollution sources and assessment of their combined effects on the environment. They will contribute to the preparation of quality standards, safety and technical standards and the working out of methodologies for environmental, health and economic impact assessment, and will also be geared towards the prevention of natural and technological hazards and towards rehabilitation of the environment. In addition to these activities, 'horizontal' aspects of the environment will be taken into account in the various courses of action.

A. *Participation in global change programmes*

The objective is to contribute to understanding of the processes governing environmental change and to assess the impact of human activities. Community participation will be concentrated on problems which will have an impact on environment policy and in areas where the Community is best placed to ensure European coordination in the framework of large international programmes while taking account of national programmes. This participation will contribute to the development of research on natural and human-induced climatic change, the interaction between biogeochemical cycles, atmospheric physics and chemistry, effects on ecosystems, physical, chemical and biological oceanography and climatic processes in general, as well as the depletion of the stratospheric ozone layer.

B. *Technologies and engineering for the environment*

The objective is to promote better environmental quality standards by encouraging technological innovation at the pre-competitive level. The two main lines of research in this field will be environmental monitoring, including remote sensing applications and the development of techniques and systems to protect and rehabilitate the environment (for example recycling, treatment of toxic wastes, of contaminated soil and of waste water, and clean technology).

C. *Marine sciences and technologies*

In the area of marine sciences and technologies, in addition to the MAST pilot programme a special effort will be made on basic know-how (including oceanography), coastal engineering and technologies for the exploration and exploitation of resources whilst respecting the environment.

D. *Research on economic and social aspects*

The objective is to improve understanding of the legal, economic, ethical and health aspects of environmental policy and management, and concerns: natural and technological risk assessment, perception and management, the economic evaluation of environmental impacts, the socioeconomic impact of the implementation of environmental policies, and the effectiveness and consistency of laws and regulations related to environmental matters.

E. *Integrated research projects*

The objective is to cooperate on interdisciplinary research into a limited number of areas of transnational interest. These transnational projects may involve coordinated campaigns, extending from observation and experimentation to integrated operations attaching to all aspects of a regional issue and encompassing general research work on natural and technological risks. Integrated research into modelling will also have to make possible assessment of technological strategies for the environment. There will also be concerted action on the databank.

The Joint Research Centre (JRC) will contribute to activities in the environmental field, in particular by prenormative work on atmospheric chemistry and on modelling, by study of the assessment and management of technological risks and by use of experimental ways of assessing such risks. The JRC will make a specific contribution to the application of remote sensing techniques in cooperation with the European Space Agency; in cooperation with the future Environment Agency of the European Community, it will contribute to the development of new instruments and trial techniques, to the harmonization of methods of measurement and to intercalibration.

4. **Life sciences and technologies**

The long-term strategic objective is to contribute in a selective and integrated way to the development of Europe's potential for understanding and using the properties and structures of living matter.

A. *Biotechnology*

The aim of this research is to reinforce basic biological knowledge as the common and integrated foundation needed for applications in agriculture, industry, health, nutrition and the environment.

All the necessary importance will be attributed to the ethical implications of such work and their relevance to industry.

The goals of the Bridge programme will be expanded. The priority areas will include protein structure and function, molecular modelling, the structure and function of genes, in particular genome analysis in representative species, the conservation of genetic resources, the expression of genes and controls thereon, cellular regeneration and development, and the reproduction and development of living organisms. Work will also cover animal and plant microbe metabolisms and their essential physiology, the ecological implications of biotechnology, with particular reference to microbe ecology and the environmental behaviour of modified genes and organisms. Communication systems within living matter, in particular immunology, neurobiology and the operation of receptors, will also be studied.

The methods and tests making up the requisite scientific prenormative bases for the preparation of Community rules will be developed.

B. *Agricultural and agro-industrial research*

The objective is to contribute to securing a better match between production of land and water-based biological resources and their use by consumers and industry. Within the pre-competitive field, sights should be set on upgrading and diversifying agricultural and sylvicultural products, on enhancing the competitiveness of agricultural and agri-food undertakings in line with other Community policies, while contributing to better rural and forestry management and to ensuring proper protection for the environment.

These will involve interdisciplinary projects which make use in particular of the findings of biotechnology and take account of genetic factors, agricultural and sylvicultural engineering, cultivation or breeding techniques, and environment-plant interaction. In particular, there will be a project to develop effective remedies for desertification and deforestation. Research in the field of aquaculture and fisheries will be pursued.

Work has already started on some topics in the second framework programme, especially under the Eclair programme. Still within the pre-competitive field, they will be supplemented by demonstration projects jointly developed by producers and users to bring the products of research and development closer to their applications.

In the field of industrial uses for agricultural and sylvicultural raw materials, still within the pre-competitive sphere, research must as a matter of priority be directed to innovative processes aimed at industrial exploitability of the by-products of food-oriented applications and at developing new, cleaner industrial and energy applications holding out favourable economic prospects.

Agri-food research already begun under the second framework programme, in particular the Flair programme, will be amplified, particularly as regards: definition and satisfaction of nutritional

needs, toxicology and food hygiene, new technologies for agri-food processing. Further work in these sectors will take account of ongoing programmes (Eclair, Flair, agricultural research and fisheries).

When these projects are being implemented, encouragement will be given to the execution of innovative projects by small and medium-sized undertakings.

C. *Biomedical and health research*

The chief objective is to contribute to improving the effectiveness of research and development in medicine and health in the Member States, in particular through better coordination of their research and development activities, to applying their findings through Community cooperation and to using available resources in common.

The main focus is on new approaches to tackling economically and socially significant diseases (in particular cancer, AIDS, cardiovascular disease and mental illness), ageing, the problems of the handicapped and the problems of health at the workplace, through harmonized methodological and protocol studies in epidemiological, biological and clinical research. Activities will also cover the analysis of the human genome and will be closely coordinated with work done elsewhere on the other genomes. Ethical, social and legal aspects of implementing the findings of research into the human genome will be carefully assessed.

This action will be supplemented by pre-competitive research into ways and forms of administering medicines.

Particular attention will be paid to methods of early screening for risk factors, to the development and assessment of prophylactic and therapeutic methods and to the management of health services.

D. *Life sciences and technologies for developing countries*

The objective of this programme is to increase cooperation in the fields of tropical agriculture (including fisheries), medicine, health and nutrition between European scientists and scientists from developing countries so as to enable the developing countries to benefit from the scientific knowledge and technological developments available in the Community and to encourage the development of their own research capacity and the Member States of the Community to increase their own capacities.

All the problems associated with tropical areas (soil, water, forests, energy, environment, agriculture, population, health, nutrition, etc.) will be taken into account.

In tropical agriculture, emphasis will be placed on integrated management of agricultural resources, including aquaculture and forestry, for reducing food shortages in regions at risk while conserving the environment with due regard for the human factor. Special attention will be paid to crops which are potential substitutes for those used for producing narcotic drugs.

Tropical medicine research will undertake new initiatives on major health problems, particularly as regards transmissible diseases and health care systems.

5. **Energy**

The main aim of Community action in this area is the development of sound, environmentally safe energy technologies designed to improve the Community's energy balance at reasonable expense within the large market. This will be pursued in the following three areas.

A. *Fossil and renewable energy sources, energy utilization and conservation*

The objective is to contribute to the development of new energy options that are both economically viable and more environmentally safe, including energy-saving technologies, by means of joint activities to assist Member States in this direction. In this connection, increased attention must be

paid to work on those energy technologies which, despite their high potential and the fact that they have no adverse effects on the environment, particularly the climate, cannot be used under satisfactory economic conditions at present as this work cannot yet be fully funded by industry.

Activities will be concentrated in three interconnected areas: energy conservation, renewable sources and reduction of the adverse impact on the environment. As regards energy conservation, account will be taken of the leading role of fossil fuels in the Community's energy supplies. This will include work on improving technologies for economizing energy in all its uses, energy production from fossil sources using advanced technologies, in particular combined cycles, and suitable substitutes for conventional fuels in the transport sector. As regards the environmental impact of producing and using energy, in particular electricity, emphasis will be placed on reducing emissions of gases responsible for the greenhouse effect, including CO_2. R & D work in the field of renewable energy sources will be stepped up to bring it rapidly up to the level where it can make an optimal contribution to the Community's energy policy.

Research into modelling should also enable technological strategies relating to energy conservation and energy-environment interaction to be assessed.

B. *Nuclear fission safety*

The aim of this action is to continue the common endeavour to support Member States in the fulfilment of their responsibilities for regulating and protecting the environment.

Community action will foster a harmonized approach to safety by bringing together all the parties involved, thus reinforcing the prenormative dimension of research. A new impulse will be given by concentrating research on reactor safety with greater attention to passive technologies, radioactive waste management, decommissioning operations, intervention in a hostile environment, fuel elements, actinides and control of fissile materials. Radiation protection research will cover radiation from natural and medical sources, a better definition of the risks of low radiation doses and new technologies to assess quickly the radiological consequences of nuclear accidents.

The Joint Research Centre will participate in this action through work in the field of reactor safety, radioactive waste safety and management, the management and safety of fissile materials, nuclear fuel and actinides.

C. *Controlled nuclear fusion*

The long-term objective of the Community fusion programme is the joint creation of safe, environmentally sound prototype reactors. The immediate objective is the establishment of the scientific and technological base for the construction of an installation designed to achieve and study the ignition and prolonged combustion of plasma and related technological problems (Next Step). Accordingly, in order to achieve control of plasma in conditions close to those of the Next Step, the Council could decide, in the light of the evaluation, to prolong the JET Joint Undertaking beyond the date currently planned. Work relating to the Next Step and the new systems will be continued taking into account developments in ITER cooperation. Following assessment of ongoing actions, work may include the building of specialized equipment necessary for attaining the objectives of the programme. Some existing fusion devices will be phased out, having completed their experimental programmes. The present keep-in-touch activity with other approaches to controlled thermonuclear fusion, and particularly with inertial confinement, will be continued.

The Joint Research Centre will make its contribution by means of work on installation safety, support for NET and some basic work on materials. This work will be closely coordinated with that undertaken in the same fields in associations.

III. MANAGEMENT OF INTELLECTUAL RESOURCES

6. Human capital and mobility

The objective is to help increase the human capital in terms of research and technological development which the Member States will be needing in the next 10 years and to make optimum use of their scientific and technical infrastructure, paving the way for a genuinely European scientific and technical community. This action should provide Community added value of benefit to all Member States.

Unlike the preceding headings, which are to be organized in a thematic or sectoral manner, this action will be organized across the board, following a bottom-up approach, around two main strands: training and mobility of research staff, and the building-up of networks.

Increased mobility of research staff will enable more of them to spend a significant amount of time during their careers working in high-level scientific and technical establishments in other Member States.

Actions will be aimed chiefly at training young people embarking on careers in research and technological development (especially at postgraduate level) and may also cover other staff, at times when they need to acquire new specializations, particularly during retraining required to adapt to rapid scientific and technological change, and in exchanges and cooperation schemes which are to be maintained on a permanent basis.

The building-up of an infrastructure of networks under this action is of crucial importance for the achievement of the objectives of the Community's research and technological development policy in consolidating and complementing the structuring effects of thematic programmes.

The networks will bring together both public and private sector laboratories and research teams from the Member States, so that they can all benefit from the experience acquired by the best amongst them. They will particularly encourage interchange between different disciplines, the grouping together of several techniques and the extension of applications from one area to another.

The networks should extend to all the regions of the countries of the Community, particularly bearing in mind the special needs of peripheral regions and regions that are currently lagging behind. Highly-qualified scientific and technical potential will thus be built up in these regions.

The activities being carried out under the Science plan will be taken further. In addition to twinning between laboratories, encouragement will also be given to projects of the same type involving both applied and industrial fundamental research, grouping together institutions from several countries or bringing together national and Community initiatives.

The effects of such action will be increased by developing cooperation between laboratories and teams of research establishments (including the Joint Research Centre), undertakings and higher education establishments.

Account must be taken of demographic factors and of the research and training structures peculiar to the various States, to help each of them to acquire the best possible capabilities.

This will also involve encouraging special access to existing major scientific facilities and fostering consultations when future facilities are being planned.

All these schemes will cover the various branches of technology, the exact and natural sciences, including mathematics and the human and social sciences, which help to strengthen the scientific and technical base of European industry and make it internationally competitive. Interfaces between basic science and technological applications will be taken into account.

Care will be taken to see that these activities have due regard to the existing bilateral and multinational cooperation to which the Member States are party, including cooperation in the COST framework.

Care will also be taken to see that they are in keeping with other Community training and research activities.

The scientific, technical and industrial community will be involved in implementing this project, particularly in identifying networks and choosing beneficiaries, with due regard for the guiding principles of the projects and for Community added value.

ANNEX III

SELECTION CRITERIA

In general, Community research and technological development (R & TD) actions should be selected on the basis of scientific and technical objectives, their scientific and technical quality and their contribution to the definition or implementation of Community policies.

A particular aim of Community R & TD shall be to strengthen the scientific and technological basis of European industry — including that of small and medium-sized undertakings — especially in strategic areas of high technology, and to encourage it to become more competitive at international level.

Community action can be justified where it presents advantages (added value) in the short, medium or long term from the point of view of efficiency and financing or from the scientific and technical point of view as compared with national and other international activities (public or private).

The following criteria in particular justify Community action:

— research which contributes to the strengthening of the economic and social cohesion of the Community and the promotion of its overall harmonious development, while being consistent with the pursuit of scientific and technical quality;

— research on a very large scale for which the individual Member States could not, or could only with difficulty, provide the necessary finance and personnel;

— research, the joint execution of which would offer obvious financial benefits, even after taking account of the extra costs inherent in all international cooperation;

— research which, because of the complementary nature of work being done nationally in part of a given field, enables significant results to be obtained in the Community as a whole in the case of problems whose solution requires research on a large scale, particularly geographical;

— research which contributes to the achievement of the common market and to the unification of the European scientific and technical area, and research leading, where the need is felt, to the establishment of uniform rules and standards.

ANNEX IV

RATES OF COMMUNITY FINANCIAL PARTICIPATION

The rates of financial participation by the Community are as follows:

— direct action will in principle be fully funded;

— concerted action may receive a contribution of up to 100 % of the costs of concertation;

— for shared-cost projects, the contribution will not normally be more than 50 %. Universities and other research centres participating in shared-cost projects will have the option of requesting, for each project, either 50 % funding of total expenditure or 100 % funding of the additional marginal costs;

— for the implementation of the activities provided for in Article 2 (2), the Council will decide for each individual case the details of the Community's financial contribution.

There may be no derogation from these general rules, except under the conditions set out in each specific programme.