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.