COMMISSION OF THE EUROPEAN COMMUNITIES

XI/323/92/EN - RE

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DG XI FOR THE QUALITY OF LIFE

HANDBOOK

FOR THE IMPLEMENTATION OF DIRECTIVE 90/219/EEC ON

THE CONTAINED USE OF GENETICALLY MODIFIED MICROORGANISMS

MAY 1992

DIRECTORATE GENERAL XI
ENVIRONMENT, NUCLEAR SAFETY
AND CIVIL PROTECTION

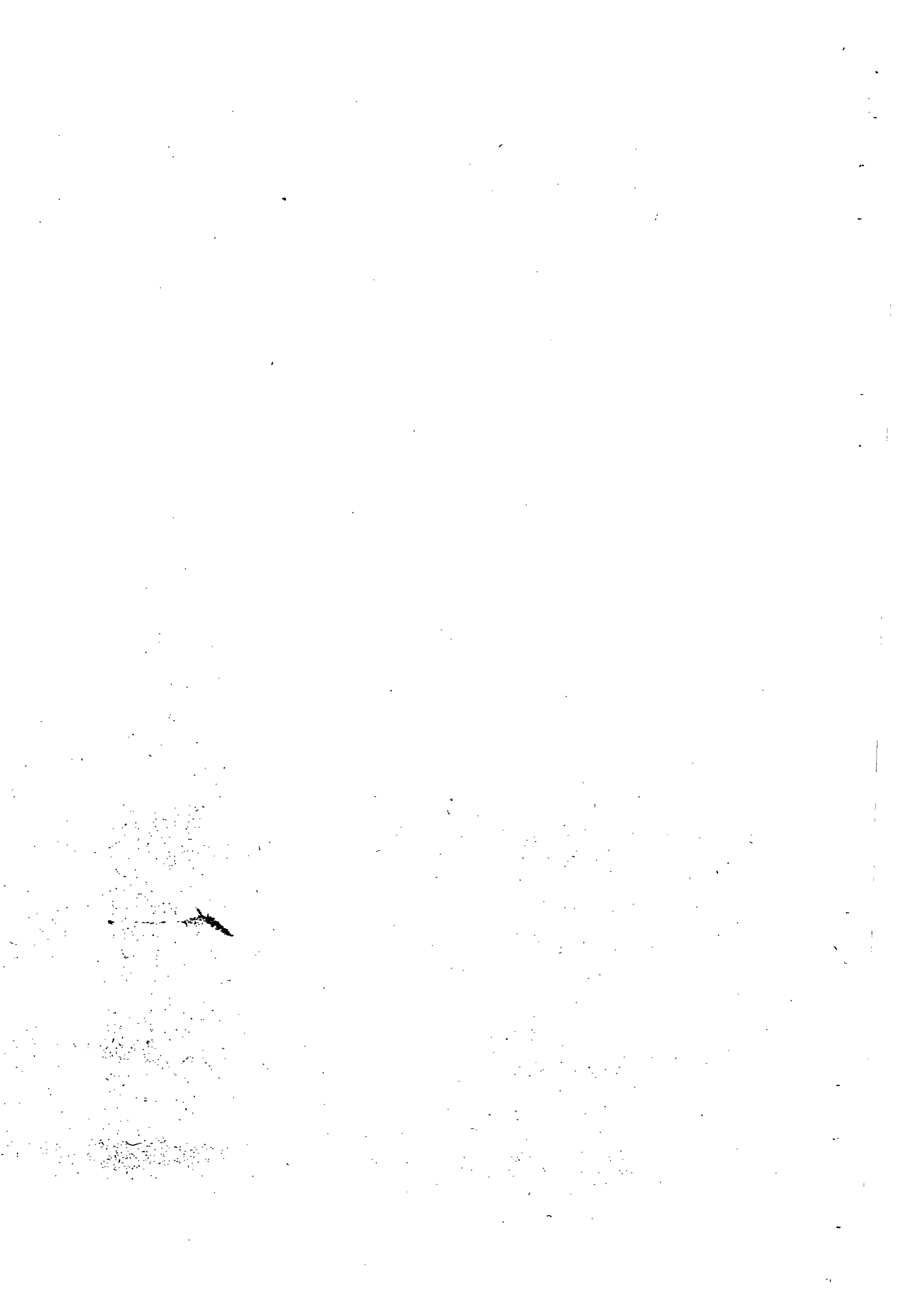
CONTENTS

FOREWORD

Since the adoption of Directive 90/219/EEC in April 1990, experts on biotechnology from the twelve Member States of the European Community have met regularly, at first as the Group of National Experts on Biotechnology and then as the Committee of Competent Authorities, to discuss details of implementing the Directive. The objective has been to reach agreement by consensus on a uniform and clear interpretation of the text, and also to prepare a number of documents referred to in the Directive. This handbook brings together the results so far achieved jointly by all the Member State Authorities, who have discussed and agreed the texts as formulated. Some of the texts have formal legal status and others not, but the principles are incorporated either in national legislation or in the administrative practice in implementing the Directive in the Member States.

The Competent Authorities and representatives from the Commission will continue to meet regularly to discuss aspects of implementation not covered by the present handbook and to revise the existing notes in light of the experience gained by the implementation of the Directive. The handbook will be revised and supplemented accordingly.

The handbook is a compilation of existing documents, providing guidance for the implementation of the Directive. It is intended to assist the Competent Authorities in their work, to guide those intending to work with GMMs, and to generally inform interested groups and the public at large. It should be noted that the content of this handbook is for information only. None of the texts modify in any way the text of the Directive nor do they prejudice the legal interpretation of the Directive which can only be provided by the Court of Justice.



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

'ANNEX II

CRITERIA FOR CLASSIFYING GENETICALLY MODIFIED MICRO-ORGANISMS INTO GROUP I

A genetically modified micro-organism is classified as falling within Group I when all the following criteria are fulfilled:

(i) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants;

(ii) the nature of the vector and the insert is such that they do not endow the genetically modified micro-organism with a phenotype likely to cause disease to humans, animals or plants, or likely to cause adverse effects in the environment;

(iii) the genetically modified micro-organism is unlikely to cause disease to humans, animals or plants and is unlikely to have adverse effects on the environment.'

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 90/219/EEC ON THE CONTAINED USE OF GENETICALLY MODIFIED ORGANISMS

EXPLANATORY NOTES

(to be read together with the text of the Directive)

EXPLANATORY NOTES FOR COUNCIL DIRECTIVE 90/219/EEC ON THE CONTAINED USE OF GENETICALLY MODIFIED MICRO-OGRANISMS

Preface

On 23.04.1990, the Council of the European Communities adopted legislation in the form of Directive 90/219/EEC laying down the procedure and conditions for the contained use of genetically modified micro-organisms in the European Community. EC Member States are obliged to implement this Community legislation at the latest by 23 October 1991.

The legal text of the Directive is published in all the Community languages in the Official Journal of the European Communities, N° L 117, dated 8.5.1990 and is available free of charge, as are all the documents referred to in these notes. (The Italian and Greek texts of the Directive were subsequently corrected in the OJ L 7, 10.1.91 and other linguistic corrections are still to be published).

These Explanatory Notes offer practical guidance to assist in the understanding and implementation of the Directive. Although the guidance is based on legal requirements, it is not intended to be an authoritative interpretation of the law; such interpretation can only be made by the European Court of Justice.

Preamble

The preamble to the Article of the Directive summarizes the contents of the Articles and highlights the significant points. It is the Articles that lay down the legal requirements but the preamble can help clarify and interpret the main body of the legal text.

The legal basis of the Directive is Article 130 of the Treaty establishing the European Economic Community, which states, amongst others, the following;

"Action by the Community relating to the environment shall have the following objectives:

(i) to preserve, protect and improve the quality of the environment;

(ii) to contribute towards protecting human health;

(iii) to ensure a prudent and rational utilization of natural resources.

Action by the Community relating to the environment shall be based on the principles that preventive action should be taken, that environmental damage should be as a priority be rectified at source, and that the polluter should pay. Environmental protection requirements shall be a component of the Community's other policies.

The Community shall take action relating to the environment to the extent to which the objectives referred to in paragraph 1 can be attained better at Community level than at the level of the individual Member States. Without prejudice to certain measures of a Community nature, the Member States shall finance and implement the other measures.

The Council, acting unanimously on a proposal from the Commission and after consulting the European Parliament and the Economic and Social Committee, shall decide what action is to be taken by the Community.

The protective measures adopted in common pursuant to Article 130 shall not prevent any Member State from maintaining or introducing more stringent protective measures compatible with this Treaty."

Article 1

The objective of this Directive is to provide a harmonized regulatory framework for all Contained Uses of GMMs (for both experimental and commercial purposes), in order to provide for the protection of human health and the environment.

The Directive does not cover contained uses of higher organisms as such, although in most cases the work with higher organisms will be covered since it will be preceded by modification work at the micro-organism or cell culture level.

The Commission has undertaken to keep the whole biotechnology sector under review and make appropriate proposals to extend the scope of this Directive to genetically modified organisms. In the meanwhile, Member States may maintain and adopt national measures, in conformity with the Treaty and any relevant Community legislation, regarding the contained use of genetically modified organisms, other than micro-organisms, until Community provisions are adopted concerning them.

Article 2

(a) This definition covers micro-organisms including viruses and viroids; cell cultures and tissue cultures, including those from plants and animals. This definition does not cover naked rDNA and naked r-plasmids.

(c) The walls of a laboratory or building may, in some circumstances, constitute physical barriers.

(d) To qualify as a Type A operation, an activity must fulfil two conditions; its purpose must fall within one of the five categories indicated, and it must be of a small scale. The example of 10 litres is indicative of small scale but not binding. More specific guidance is being developed by the Commission together with the Member State authorities to clarify further the concept of small scale for the purpose of Type A operations. (Ref: document XI/535/91)

Article 3

Certain GMMs are excluded from the scope of this Directive.

Member States may maintain or adopt national measures, in conformity with the Treaty and relevant Community legislation, regarding the contained use of those genetically modified micro-organisms to which this Directive does not apply.

Article 4

For the purposes of the Directive, two risk groups of GMMs are established, Group I and II respectively, using as the basis of the criteria of Annex II. Any GMM used in a specific operation must be classified in one of the two groups, Group I or II.

Further guidelines for interpreting Annex II, both for Type A and Type B operations have been established by the Commission together with the Member State authorities (OJ L 239, dated 28.8.91). The Directive also provides Member State authorities the flexibility to apply slightly different, but equivalent, criteria for provisionally classifying some GMMs into Group I, but only for GMMs to be used in Type A operations.

Article 5

Transport of GMMs is excluded from the Directive for those GMMs which have been placed on the market under Community legislation following a specific risk assessment. For all other cases of GMMs, transport is excluded as regards the notification procedures and containment measures, but not as regards the overall scope (as defined in Articles 1-4), nor the requirement to make a risk assessment (Article 6) or to take precautions in the case of accidents (Articles 14-17). However, transport is excluded from the requirements of Articles 7-12, and more specific measures for transport will be the subject of separate Community legislation under preparation.

Article 6

Member States have the obligation both to take measures themselves (legal, administrative and practical) and to lay down measures that need to be taken by those carrying out a contained use of GMM in order to avoid adverse effects on human health and the environment. The measures referred to cover both general and specific measures, and can be before or during a contained use, as appropriate.

In order to ensure that adverse effects are avoided, all persons intending to use a genetically modified micro-organism must carry out a prior risk assessment of the proposed operation taking into account the factors outlined in Annex III to the Directive. A summary of this assessment is submitted to the authorities as part of the notification.

For Type A operations using Group I organisms, this summary is only provided on request, as no notification is submitted.

A full record of the assessment is kept by the user in all cases and must be made available on the request of the authorities.

Article 7

The safety principles to be followed and measures to be taken are outlined here. For work with Group II organisms, specific containment categories are foreseen in Annex IV to ensure a high level of safety.

The Commission has undertaken to keep the problems relating to Type A operations under review and to make proposals, if necessary, to specify further the containment measures to be applied and the criteria for placing Type A and Type B operations in specific containment categories.

The user has an obligation to review containment provisions in order to ensure that the latest technical knowledge is incorporated in the measures taken.

Article 8

When carrying out work with GMMs for the first time in a particular installation, the user must notify the competent authority so to register the installation and allow any appropriate controls to be carried out.

If an installation notified for work with Group I GMMs is to be used for work with Group II GMMs, a new notification must be made.

Article 9

Once the installation has been registered at the time it is first used, as outlined in Articles 8 and 11.4, a simplified procedure is envisaged in the case of Type A operations using group I micro-organisms. Records of work are to be kept and made available to the competent authorities on request.

For Type B operations using Group I GMMs, a notification must be forwarded to the competent authorities containing the information required in the relevant part of the Annex.

Article 10

Anyone wishing to undertake either a Type A or a Type B operation using Group II GMMs must submit a notification to the authorities containing the information outlined in this Article and in the relevant annexes.

Article 11

Competent authorities for the contained use of GMMs must be designated by Member States, by 23.10.1991 at the latest. If competent authorities are not designated by that date in a Member State, infringement procedures for non-compliance with the Directive will be started by the Commission. Annex I of these explanatory notes gives details of the authorities so far formally designated in the Community according to Directive 90/219/EEC.

The competent authorities are responsible for examining the notifications and its conformity, including the correctness of the classification made and the risk assessment carried out by the user, and can request further information if appropriate. The authorities are also responsible for issuing an approval of the installation or activity, where appropriate, and for placing conditions on the contained use, where necessary.

When an installation is notified to the authorities (first time use), if it is to be used for work with Group I GMM only, it can be considered as approved if no indication to the contrary is received from the competent authority within 90 days of the submission. If the installation is to be used for work with Group II GMMs, a written consent must be given by the authorities within this 90 day period.

When specific Type B operations are to be carried out with Group I GMMs, or Type A operations with Group II GMMs, notification has to be submitted as specified under Article 9.2 and 10.1, and the operation can go ahead if no indication to the contrary is received from the authorites within 60 days.

If the operation is of Type B with Group II organisms, a specific written consent needs to be given within 90 days of submission of the notification.

Article 12

Even after the notification has been submitted, or even approved, the notifier still has the responsibility to provide to the authorities any additional information which could have significant consequences for the risk posed. If the GMM used is reclassified in another Group or another GMM is used in the operation, the authorities must be notified immediately and the appropriate steps must be taken. The competent authority also has the possibility to come back to the notifier and require modification of the terms of the use or suspension or termination of the activities, if this is considered necessary following the availability of new information concerning risks.

Article 13

Member States have the possibility to make wider consultations concerning any aspect of a contained use, provided that confidentiality is respected as outlined in Article 19.

Article 14

The Directive places a requirement on the authorities to ensure that emergency plans are drawn up, where necessary, before an operation commences, and that information on safety is made available to all those liable to be affected, as well as to other Member State authorities.

Article 15

The Directive places an obligation on the user to notify the authorities in case of an accident.

Competent Authorities must ensure that the necessary emergency, medium and long term measures are taken and alert any other Member State which could be affected by an accident and take the necessary steps to avoid similar accidents in future.

Article 16

Provision is made for Member States to consult each other concerning accident prevention and dealing with accidents. A procedure for a system for exchange of information has been established by the Commission together with Member States Authorities. (Ref: document XI/642/90)

Article 17

Inspections and other control measures are important to ensure compliance, and there is an obligation on Member States to plan for these.

Article 18

A first report from Member States summarizing experiences with the Directive is to be sent annually to the Commission regularly, the first time being 1 September 1992. The Commission will subsequently publish its own summary report, the first time being in 1993. Suggested outlines for the Member States summary reports will be provided.

Article 19

The confidentiality provisions outlined in this Article are of extreme importance. The Commission has established together with the Member States authorities a system of specific security procedures and measures to ensure the protection of confidential information at all levels.

The Commission has the responsibility to ensure that the confidentiality provisions are adhered to and absence of suitable measures in Member States will be considered as an infringement. One practical effect of this will be that confidential information will not be received by that Member States from the Commission or other Member States.

At the same time, it is also important that certain information is made available as outlined in Article 19.4. The Commission is establishing together with the Member State authorities, guidance concerning this aspect.

Article 20

As new technical information becomes available, it is foreseen that some of the annexes will be adapted to technical progress.

Article 21

The Committee foreseen to assist the Commission, has several important functions, as outlined in the Directive. It will be chaired by the Commission, consist of representatives formally appointed by the Member States, and will operate according to the internal rules it adopted at its first meeting on 5 July 1991 in Brussels. (Ref: Document XI/325/91)

The votes of Member States in the Committee are weighted as follows: Belgium 5, Denmark 3, Germany 10, Greece 5, Spain 8, France 10, Ireland 3, Italy 10, Luxembourg 2, Netherlands 5, Portugal 5 and United Kingdom 10.

To be adopted, a proposal put to the Committee by the Commission must receive 54 votes in favour.

Article 22

The implementation date of 23 October 1991 was the deadline for Member States to adopt their own legislation. In order to be implemented in a Member State, the Directive has to be transposed in its entirety and in all the regions of a Member State.

If a Member State does not implement fully or correctly the Directive, the Commission will take the necessary steps to start infringement procedures as foreseen under Article 169 of the Treaty.

Member States have to officially inform the Commission of their legislation as soon as they adopt it. Once the Commission has been informed of legislative measures taken, it will examine them to ensure conformity with the Directive. If there is no conformity, Member States will be notified and asked to take the necessary measures. If they do not comply, infringement procedures will be started.

Article 23

The Directive is a piece of legislation addressed only to the Member States governments who in turn are responsible for taking the necessary action for implementation.

XI/12/92-Rev.2

COMPETENT AUTHORITIES FORMALLY APPOINTED BY MEMBER STATES TO BE RESPONSIBLE FOR THE IMPLEMENTATION OF DIRECTIVE 90/219/EEC

DENMARK

The Ministry of Environment
Slotsholmsgade 12
DK - 1216 KOBENHAVN K

Ministry of Labour
National Labour Inspection Service
Landskronagade 33-35
DK - 2100 COPENHAGEN Ø

FEDERAL REPUBLIC OF GERMANY

The full list of Competent Authorities of the Federal Republic is annexed. The Authority acting as a contact point with the Commission is:

Bundesministerium für Gesundheit
Referat 353
D - 5000 BONN 2

SPAIN (provisional appointment)

Secretarià de Estado para las Politicas de Agues
y Medio Ambiente
Paseo de la Castellana 67
E - 28071 MADRID

FRANCE

Ministère de l'Environnement
DEPPR
14, Bd. du Général Leclerc
F - 92524 NEUILLY-SUR-SEINE

Ministère de la Recherche
DGRT
1, Rue Descartes
F - 75231 PARIS CEDEX

ITALY (provisional appointment)

Ministero della Sanità
Via Sierra Nevada 60
I - 00144 ROMA

NETHERLANDS

Ministry of Housing, Planning and Environment Protection
Directorate General for Environment Protection
Postbus 450
NL - 2260 MB LEIDSCHENDAM

PORTUGAL

Direcção Geral Qualidade Ambiente
Rua Século 51-1°
P - 1200 LISBOA

UNITED KINGDOM

Health and Safety Executive
Baynards House
1, Chepstow Place
UK - LONDON W2 4TF

Department of the Environment
Romney House
43 Marsham St.
UK - LONDON SW1 3PR

BELGIUM

Flemish Region
Administratie Milieu, Natuur en
Landinrichting
Kunstlaan 43
B - 1040 Bruxelles

Wallonian Region
Direction Générale des Ressources
naturelles et de l'Environnement
Division de la Prévention des Pollutions
Avenue Albert I, 187
B - 5000 Namur

Brussels-Capital Region
Institut bruxellois pour la gestion
de l'Environnement
Avenue Louise 149
B - 1050 Bruxelles

Contact Point:
Institute of Hygiene and Epidemiology
Biosafety rDNA and Biotechnology
J. Wytsmanstraat 14
B - 1050 Bruxelles

ANNEX

FEDERAL REPUBLIC OF GERMANY – FULL LIST OF COMPETENT AUTHORITIES

COMPETENT MINISTRIES	COMPETENT AUTHORITIES FOR NOTIFICATIONS AND AUTHORISATIONS
Baden-Württemberg	
Ministerium für Umwelt Kernerplatz 9 D – 7000 Stuttgart 1	Regierungspräsidium Konrad-Adenauer-Str. 10 D – 7400 Tübingen
Bayern	
Bayerisches Staatsministerium für Landesentwicklung und Umweltfragen Postfach 810 140 D – 8000 München 81	Regierung von Oberbayern Maximilianstr. 39 D – 8000 MÜnchen 22 Regierung von Oberfranken Ludwigstr. 20 D – 8580 Bayreuth Regierung von Unterfranken Peterplatz 9 D – 8700 Würzburg
Berlin	
Senatsverwaltung für Stadtentwicklung und Umweltschutz Lentzeallee 12–14 D – 1000 Berlin 33	Senatsverwaltung für Stadtentwicklung und Umweltschutz Lindenstraße 20–25 D – 1000 Berlin 61
Senatsverwaltung für Soziales Abt. V An der Urania 4–10 D – 1000 Berlin 30	Senatsverwaltung für Soziales Urania 4–10 D – 100 Berlin 33
Brandenburg	
Ministerium für Umwelt, Naturschutz und Raumordnung Albert-Einstein-Str. 42–46 D – 1591 Potsdam	Institut für Arbeitsschutz und Arbeitsmedizin der Landes Brandenburg An den Kopfweiden 10 D – 1561 Potsdam
Freie und Hansestadt Bremen	
Senator für Gesundheit Birkenstraße 34 D – 2800 Bremen 1	Senator für Gesundheit Birkenstr. 34 D – 2800 Bremen 1

Freie und Hansestadt Hamburg

Umweltbehörde Hamburg
Hammer Land Str. 12–14
D – 2000 Hamburg 26

Umweltbehörde Hamburg
Hammer Land Str. 12–14
D – 2000 Hamburg 26

Hessen

Hessicher Minister für Umwelt,
Energie und Bundesangelegenheiten
Dostojewskistr. 4
D – 6200 Wiesbaden

Regierungspräsident Gießen
Land-Graf-Philipp-Platz 3–7
D – 6300 Gießen

Mecklenburg-Vorpommern

Sozialministerium
Werderstr. 124
D – 2750 Schwerin

Sozialministerium, Ref. 311
Werderstr. 124
D – 2750 Schwerin

Niedersachsen

Niedersächisches Umweltministerium
Archivstraße 2
D – 3000 Hannover 1

Bezirksregierung Braunschweig
Dezernat 204
Bohlweg 38
D – 3300 Braunschweig

Bezirksregierung Hannover
Dezernat 234
Am Waterlooplatz 1
D – 3000 Hannover 1

Nordrhein-Westfalen

Ministerium für umwelt,
Raumordnung und Landwirtschaft
Schwannstr. 3
D – 4000 Düsseldorf 30

Regierungspräsident Arnsberg
Seiberstr. 1
D – 5160 Arnsberg 2

Regierungspräsident Düsseldorf
Cecilienallee 30
D – 4000 Düsseldorf 30

Regierungspräsident Münster
Domplatz 1/3
D – 4400 Münster

Regierungspräsident Detmold
Leopoldstr. 13/15
D – 4930 Detmold

Regierungspräsident Köln
Zeughausstr. 4/10
D – 5000 Köln 1

Rheinland-Pfalz

Ministerium für Umwelt
Kaiser-Friedrich-Str. 7
D - 6500 Mainz 1

Landesamt für Umweltschutz und
Gewerbeaufsicht
Amtsgerichtsplatz 1
D - 6504 Oppenheim

Saarland

Ministerium für Umwelt
Hardenbergerstr. 17
D - 6600 Saarbrücken

Ministerium für Umwelt
Hardenbergerstr. 17
D - 6600 Saarbrücken

Sachsen

Staatsministerium für Umwelt
und Landesentwicklung
Ostra-Allee 23
D - 8010 Dresden

Staatsministerium für Umwelt
und Landesentwicklung
Ostra-Allee 23
D - 8010 Dresden

Sachsen-Anhalt

Ministerium für Umwelt und
Naturschutz des Landes Sachsen-Anhalt
Postfach 3769
D - 3010 Magdeburg

Bezirksregierung Magdeburg
Olvenstedter Str. 1/2
D - 3010 Magdeburg

Schleswig-Holstein

Minister für Natur, Umwelt und
Landesentwicklung des Landes
Schleswig-Holstein
Postfach 6209
D - 2300 Kiel 14

Ministerium für Natur, Umwelt
und Landesentwicklung des Landes
Schleswig-Holstein
Postfach 6209
D - 2300 Kiel 14

Thüringen

Ministerium für Soziales und
Gesundheit
Werner-Seelenbinderstr. 14
D - 8085 Erfurt

Ministerium für Soziales und
Gesundheit
Werner-Seelenbinderstr. 14
D - 8085 Erfurt

GUIDANCE FOR IDENTIFICATION OF TYPE A OPERATIONS ACCORDING TO DIRECTIVE 90/219/EEC

1. Background

Article 2(d) of the Directive defines a Type A operation as any operation used for teaching, research, development, or non-industrial or non-commercial purposes and which is of a small scale. Both the conditions of purpose and of small scale need to be fulfilled at the same time. Culture volume of 10 litres or less is given as an example of small scale in the Directive. It should be clear that culture volume is not the only factor determining whether an operation is Type A. In fact, the purpose of the operation is very important, e.g. whether it is research work in laboratory facilities, or whether the purpose is to optimize production parameters under production conditions.

Type A operations are typically characterised by work with small numbers of organisms under good laboratory practice and under rigorous surveillance and controls. The work can be basic science or applied research, carried out either in a university laboratory or in the laboratory of a commercial firm with the purpose of creating a process for industrial or commercial exploitation.

Those operations which do not fulfil the criteria for Type A operations are categorised as Type B operations. A Type B operation is frequently carried out either in a full scale production plant or in a pilot plant facility.

Type B operations will in the main be carried out under industrial conditions. Usually production volume is considerably greater than in Type A operations, and operational conditions are different. Where a Type B operation is industrial production, this is characterized by being a process or series of processes that are repeated again and again with little or no changes in process conditions and which lead to a product that is either put on the market or used as raw material somewhere in the production.

The Directive stipulates that Type A operations using Group I organisms and taking place in notified installations can proceed without any specific notification of the competent authorities. The user has to keep records of the work carried out, and these must be made available to the competent authority on request (Article 9, paragraph 1). Type A operations with Group II organisms need to be notified.

The Directive requires notification procedures for all Type B operations, and for those using Group II organisms the user has to wait for the consent of the competent authorities as specified in Article 11.

2. Difficulties in defining small scale

The definition of small scale widely acceptable in many countries since the end of the 1970s has been fermentation in volumes of 10 litres or less. In a majority of applications, this volume indication has been a useful and well understood guideline. Experience has so far shown that many research and development applications do not exceed 10 l in volume.

It must however be recognized that the 10 l guidance cannot always be applied for defining small scale and has certain limitations:

i) It only involves the fermentation volume and makes no reference to the number of recombinant organisms present.

ii) It does not take into account the need to carry out research trials in fermenters with a capacity greater than 10 litres, which may be necessary because of the growth characteristics of the organism.

iii) The 10 litres indication relates mainly to liquid media batch fermentation in laboratory vessels. However, other techniques are used in research, such as continuous fermentation, reverse osmosis, solid media cultures and propagation in animals and plants.

iv) There are difficulties in making a link between volume and risk and also in deciding what "small scale" is for the purpose of safety measures and procedures to be followed, when the operation involves the use of multiple small containers (e.g. a series of flasks in shaking culture experiments or a number of small fermentors in series). Even when the volume of any single flask does not exceed one litre, the total volume of an operation could well be 25-50 l.

3. The need for a flexible approach to small scale definition for Type A operations

Many research and development operations are carried out at a small scale not greater than the 10 l example given, and for many procaryotic host systems in particular, the 10 litre indication is valid and applicable. However, it has to be recognized that there are special cases where there is a need in many aspects of research to work with larger volumes. An example is the development of new yeast strains where laboratory fermenters in excess of 100 litres are used. Such work could be considered small scale until scaled up for pilot plant purposes. Further examples are bottom fermentation by yeasts which cannot be simulated in a 10 l vessel, the study of genes which are only weakly expressed, anaerobic fermentation or other work with slow growing GMMs and experimental fermentation to produce proteins for further research. Although the organisms are usually in Group I, there could be a need for research with Group II organisms to be carried out in volumes greater than 10 l e.g. the study of the passage of genetically modified microorganisms pathogenic to fly larvae through a model of the alimentary system of ruminants or research using modified animal cell cultures for developing vaccines.

All this points to the need for a flexible interpretation of small scale. However, even though "small scale" is a relative concept as compared to large scale, it is a question of legal interpretation to decide by how much the example of 10 l in the Directive may be exceeded.

Flexibility in the volumes considered as "small scale" is important in certain areas of activity such as brewing because of the organisms used, but it does not seem possible to provide any particular guidance per sector at this stage since so much is dependent on the operation itself and the organism used.

It should be highlighted that the actual volume of fermentation is not a sufficient criterium for discriminating between non-production (= non-industrial) and non-commercial activities on one hand and production/commercialization on the other. World markets for rare hormones, monoclonal antibodies and special enzymes could well be met by small scale productions. The purpose of the activity, and the conditions under which it is carried out are very important elements.

4. Guidance for identifying Type A operations

When deciding whether an operation for research, development, etc. is Type A even though its volume exceeds the 10 l indicative figure in Directive 90/219, some general and some specific considerations should be taken into account:

A. General Considerations

(i) Information submitted for the first use of an installation

When a particular installation is to be used for the first time for operations involving contained use of micro-organisms, the user submits a notification to the Competent Authority (Article 8) containing the information required in the relevant parts of Annex V. The quality of information provided on the facilities and procedures, and on the microorganism to be used (Group I or Group II etc.), will be important for the Competent Authorities when considering the classsification into Type A or Type B operations.

(ii) Training and Management Practices

Where education of the staff and management are well established, the operational procedures are likely to be handled more precisely and delicate than on premises where laboratory management has a low priority. This could influence the acceptability of a larger experimental volume.

(iii) Type of general oversight practiced by the authorities

In countries where the authorities use the possibilities provided by the legislation to have a clear overview of all Type A activities for both Group I and Group II activities (e.g. by requesting registered installations to send in an annual retro-active notification for Group I Type A activities), it will be easier for the authorities to implement a more flexible approach towards the definition of small "scale".

The legal and practical possibilities for inspections, and the quality and frequency of the inspections which competent authorities are able to undertake, will also have an impact on how flexible they feel they can be on defining "small scale", since the operating conditions will be subject to some supervision if inspections are carried out.

B. More specific points to consider

(i) The practice and conditions of operation

Whether laboratory practices or industrial practices are used should be an important determining factor for considering higher volumes as Type A operations. If higher volumes are used, it must be possible to render the organisms inactive easily by standard laboratory decontamination methods.

(ii) The possibility to contain spillages and downstream handling

Other things being equal, it is easier to prevent accidental spills and releases of microorganisms from a small volume than from a great one. If greater volumes are used, additional precautions may need to be taken. In principle, the release of genetically modified microorganisms from a Type A contained use should be minimized in order to limit the contact with man and the environment. For that purpose the treatment of spills and disposals should be well organized.

Whether there is downstream processing after the fermentation stage (e.g. for extracting the organism) or not, is a factor that needs to be taken into consideration.

(iii) Physical Conditions and Containment

For the safety of Type A operations the technical state of the general laboratory facilities and equipment are important factors. The standard of the facilities will have an impact on their suitability to handle larger volumes as a Type A operation. The containment level used is also an important factor to consider, in particular for Group II operations. If the containment provisions and the equipment are well adapted to handle larger volumes, it will be easier to consider an operation as a Type A operation.

(iv) Culture density

Micro-organisms have different growth characteristics. Where numbers of cells per volume unit is low during the fermentation process it might be regarded as a useful indicator additional to volume to be used in determining "small scale"

(v) Type of operation

The exact purpose of the operation should be examined. It may, for example, be appropriate to indicate that for teaching purposes it is pertinent not to work with larger volumes of contaminated broth, either in batch or continous fermentation. The flexibility in volume may need to be specific to some of the activities described in the definition of Type A.

(vi) Type of media/type of fermentation

When continuous fermentation is used, the total amount of contaminated material produced per activity should be used in calculating volumes. It is difficult to determine specific volumes for solid media. In any case, solid media should be used in standard laboratory equipment and contaminated media should be disposed after autoclaving or incineration. Contaminated animals or plants should be effectively contained and disposed.

XI/642/90-Fin

Proposal for a Community-wide system for exchange of information on accidents

In accordance with Directive 90/219/EEC
(Article 16)

Introduction

Directive 90/219/EEC contains a number of important provisions concerning accidents, covering accident prevention, information to those liable to be affected by an accident, emergency measures to be taken in case of accident, reporting of accidents by the users to the national authorities, reporting of accidents by the national authorities to other Member States and the Commission, and the establishment by the Commission of a register of accidents.

This document is concerned only with part of the provisions concerning accidents and proposes a system for exchange of information and exchange of experience at Community level between the Member States and the Commission, as specified by Article 16 of Directive 90/219/EEC.

For the purpose of the information exchange system, the directive definition of accident is considered adequate. This defines "accident" as "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".

With respect to accident reporting and information exchange, the Directive specifies that

(i) Member States must

- ensure that a user immediately informs the competent authority in the event of an accident, providing specified information;
- ensure that appropriate emergency measures are taken;
- alert immediately any Member State which could be affected by an accident;
- collect information for a full analysis of the accident, make recommendations to avoid similar accidents and limit their effects;
- consult in advance with other Member States liable to be affected by an accident in the drawing up and implementation of emergency plans;

- inform the Commission as soon as possible of any accident and provide specified information, an analysis of the accident, and recommendations to avoid similar accidents and limit their effects.

(ii) The Commission

- shall establish, in consultation with the Member States, a procedure for exchange of information on accidents and emergency plans;

- shall set up and keep at the disposal of the Member States a register of accidents which have occured, including an analysis of the causes of the accidents, experience gained and measures taken to avoid similar accidents in future.

- may publish general statistical information on accidents and the implementation of the relevant provisions.

Outline of purpose and principles of information exchange system

An information exchange system will serve several purposes. While the overall purpose is to make it possible to alert Member States to accidents in other Member States so that they can take the necessary measures if appropriate, the information will form a good background for building up experience on a Community-wide basis on safety measures and procedures as well as on measures useful for preventing, controlling, monitoring, and mitigating effects of accidents. As such, the information exchange system should also prove useful when emergency plans are developed and discussed, and also for consultations between Member States when drawing up and implementing emergency plans (article 16).

The information exchange system will also serve to provide the necessary information for the Commission and all competent authorities to be able to respond to enquiries in case of an accident or provide any technical assistance if necessary.

The availability of accurate information on any accidents is crucial if the Community is to both prevent their occurrence and respond to them effectively. The quality and quantity of information held must be high in order to achieve these objectives. The quality of the data will depend upon the reports received from Member States.

The following can be considered as the basic principles underlying an information system:

(i) Exchange of information and consultation on emergency plans

Member State authorities must ensure, where necessary, that emergency plans are drawn for the protection of human health and the environment outside the installation in the event of an accident, and that other Member States liable to be affected are consulted in the drawing up and implementation of these plans. It is important for contact points to be established to receive information on emergency plans, and that a consultation scheme is efficient and easy to operate. This can be done by transmitting the draft emergency plans to the Commission, who will then circulate them within one week to Member States liable to be affected, who then have 30 days in which to give their views.

(ii) Early warning of an accident and its possible consequences

Even though the nature and extent of an accident only in some cases may call for an immediate reaction from other Member States while other accidents do not need any action and could theoretically be reported with some delay, it is important to have a report of all accidents as soon as possible under the Community-wide information scheme. Apart from other considerations, it is particularly important that in case of an accident all Competent Authorities, as well as the Commission, can reply to any questions or enquiries from political institutions (Parliament, ...) or the public at large.

Early warning of an accident means that the Competent Authority of the Member State where the accident occurred transmits immediately to other Member States which could be affected by the accident and to the Commission any available information , however limited, on the accident and its consequences.

In transmitting the information, the Competent Authority should indicate precisely what items of information are considered confidential, if any.

In order for an early warning system to operate effectively, all Member States should appoint a contact person in a Competent Authority who will be able to receive and react on any information of an accident.

(iii) Rapid transmission of information for prevention purposes

The information contained in detailed accident report can help to identify specific measures which, if applied, would have prevented the accident or reduced its consequences; this kind of information can be very useful for all Competent Authorities in order to prevent accidents which could occur in similar installations located in their territory, and therefore it is desirable that Member States should transmit rapidly the relevant information to the Commission, which will then transmit it to other Competent Authorities.

(iv) Accident analysis and recommendations - Exchange of experience

Article 16. 1(b) of the Directive foresees that Member States should analyse any accident which has occurred and make recommendations to limit its effect and avoid similar accidents in future, and transmit this to the Commission. This is an important element for exchange of experience, and the Commission will gather together all the information and experience gained in a register of accidents.

(v) Availability of specific and of general information

The specific and detailed information gathered by the Commission on accidents should be available to other Member States - at a first stage in the form of a table summary distributed at regular intervals. It may be important, however, for other competent authorities to have the full accident reports. This could be obtained by the Competent Authorities from the Commission, upon request.

For more general information, the Commission will make available statistical information on accidents, which will not contain any information likely to harm the competitive position of a user.

Outline of proposed information exchange scheme and its practical implementation

1. Establishment of List of National Authority and Commission contact points to be informed in case of an accident (see Annex I), and also to be contacted for emergency plans.

2. Where necessary, at the time of drawing up emergency plans, consultation of other Member States liable to be affected is carried out via the Commission. The draft plans are sent to the Commission who circulates them to the appropriate Member State within a week, giving them further 30 days to react.

3. Where necessary, at the time of an accident, early warning by telex/fax to other Member States which could be affected by the accident and to the Commission.

4. Following an accident, immediate reporting to the Commission by Member States of basic details including: site, organisms involved, effects, emergency measures taken and immediate precautions (see Annex II, part A).

5. Circulation by the Commission of basic details to other Member States within 1 week at the latest.

6. Further reporting of the incident by Member States including more detailed description, accident investigation, damage to man and the environment, and consequences, within 2 months (see Annex II, part B).

7. Compilation by the Commission of detailed accident data in a register of accidents and circulation of relevant data to other Member States. Creation of an accident documentation centre to assist preventive measures.

8. Periodic publication by the Commission of general statistical data.

Annex I-

Directive 90/219/EEC

List of national contact points in Member States in case of accidents involving genetically modified organisms with respect to Council Directive 90/219/EEC on the Contained Use of Genetically Modified Micro-oganisms

1. Member State:

2. Contact point (authority/organisation):

3. Complete address:

4. Name(s) of responsible person(s):

5. (a) Telephone:

   (b) Telex:

   (c) Fax:

6. If different term above, name and adress of responsible person to be contacted concerning emergency plans.

Directive 90/219/EEC

INFORMATION TO BE SUPPLIED TO THE COMMISSION BY THE MEMBER STATES IN WHICH AN ACCIDENT HAS OCCURED, PURSUANT TO ARTICLE 16

PART 'A' - IMMEDIATE REPORT OF ACCIDENT

Member State:

Authority responsible for report:

Address:

1. General data

Date and time of the accident:

Name of company/research institution:

Address:

Grid reference:

Principal Activity of installation .....
.....

Type of installation: A |___| B |___|

Type of activity: Group I |___| Group II |___|

2. Type of accident

Failure of equipment (breakage/leakage etc.) |___|

Fire - |___| Explosion |___|

Maloperation of equipment (human/mechanical) |___|

Other (specify) .....

3. Organisms released

Identity of genetically modified organisms released:

Quantity of genetically modified organisms released:

Form and/or concentration in which organisms released:

4. Description of the circumstances of the accident

5. Was there any emergency plan drawn up in advance? Yes |__| No |__|

If yes by whom? .....

6. Emergency measures taken

(a) Inside the installation .....
.....

(b) Outside the installation .....
.....

7. Assumed or established cause(s) of accident

Known (to be specified): ..... |_____|

Not known: |_____|

Information will be supplied as soon as possible |_____|

8. Nature and extent of exposure

(a) Within the installation:

- persons exposed to the accident |_____|
- casualties |_____|
- damage to health |_____|
- material damage |_____|
- damage affecting the containment equipment |_____|
- the danger is still present |_____|

If yes, specify .....
.....

- the danger no longer exists |_____|

(b) Outside the installation/to the environment:

- persons exposed to the accident |_____|
- casualties |_____|
- damage to health |_____|
- types of environments exposed (water, sewage systems, agricultural land, natural environments) .....

- material damage |_____|
- damage affecting the containment equipment |_____|
- damage to the environment |_____|
- the danger is still present |_____|

If yes, specify .....
.....

- the danger no longer exists |_____|

9. Member States already informed bilaterally of the accident

PART 'B' - FURTHER REPORTING, ANALYSIS AND RECOMMENDATIONS

1. Analysis of the causes of the accident

2. Analysis of the efficiency of emergency plans

3. Experience gained

4. Results of any formal accident investigation (if relevant)

5. Medium and long-term measures, particularly those aimed at preventing the recurrence of similar accidents

6. Actions taken to inform the public on the accident

7. Monitoring within and outside installations following the accident

8. Final overall assessment of damage to health and the environment

9. Recommendations for avoiding similar accident in future

Doc. XI/325/91-fin

RULES OF PROCEDURE FOR THE COMMITTEE ON

THE CONTAINED USE OF GMMS

The Committee on the contained use of GMMs,

HAVING REGARD to the Council Directive 90/219/EEC(1) of 23 April 1990 on the contained use of GMMs and, in particular, Article 21 thereof.

HAS LAID DOWN ITS RULES OF PROCEDURE AS FOLLOWS:

Article 1

1.1 The Committee shall be convened by its Chairman, either on his own initiative or at the request of the representative of a Member State.

Article 2

2.1 The Chairman shall draw up the agenda and any question, the discussion of which has been requested in writing by the representative of a Member State, must be dealt with in a Committee meeting as soon as possible and within a maximum of three months of receipt.

2.2 In the case where the Commission must carry out extensive preparatory work on the draft provisions which are submitted to the Committee, the maximum time limit is six months.

Article 3

3.1 Letters convening meetings, the agenda, draft provisions and any other working documents shall be sent by the Chairman to the Member States' representatives on the Committee in accordance with the procedure provided for under Article 11, Para. 2. These documents must reach the Permanent Representations of the Member States not later than 28 days before the meeting is due to take place, in all the Community languages.

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(1) O.J. N° L117 of 8.05.1990

3.2 In urgent cases, at the request of the representative of a Member State or on his own initiative, the Chairman may reduce this period to no less than 14 days, stating his reasons thereof.

3.3 In case of non respect of these limits, the meeting shall be postponed by the Chairman to a later date if the representative of a Member State requests it.

Article 4

4.1 The Committee delivers its opinion on the measures proposed by the Commission, according to the procedures laid down in Article 21 of Directive 90/219/EEC.

4.2 In the event that an Opinion is requested on a text to which an amendment is made during the discussion, the Chairman:

- may defer the vote to the end of the meeting or to the following meeting, whose date must then be fixed;
- must postpone the vote until the following meeting, whose date must then be fixed, if requested to do so by the representative of a Member State.

Article 5

5.1 Where the Committee has not issued an Opinion within the time limit set by the Chairman, the latter may postpone the vote until the following meeting.

Article 6

6.1 Each Member State shall appoint its representative to the Committee. The Commission will only cover the expenses for two representatives per Member State. A Member State can represent one other Member State. The Chairman shall be informed thereof by the Permanent Representation of the Member State thus represented.

6.2 The quorum required for the deliberations of the Committee to be valid shall be that required to render an opinion according to the procedures laid down in Article 21 of Directive 90/219/EEC.

Article 7

7.1 The Secretariat to the Committee shall be provided by the Commission's services.

Article 8

8.1 Before any opinion is requested from the Committee, any amendments proposed to the drafts previously circulated as mentioned under Article 3 shall be submitted to it in writing.

8.2 A list of the decisions made shall be presented to the Committee before the end of the meeting for approval. In addition, a summary of the conclusions of each meeting shall be prepared and submitted to the Committee for approval at a subsequent meeting.

Article 9

9.1 The Committee may set up sub-Committees, chaired by the Commission, to prepare its work or carry out specific tasks. The Members of these sub-Committees must be appointed by the Member States. Sub-Committees will only play an advisory role and will not have power to vote.

Article 10

10.1 The Committee may grant a hearing to non-governmental experts if there is no opposition on the part of any representative of a Member State. These experts shall take no part in either the deliberations or the voting of the Committee.

Article 11

11.1 All correspondence concerning the Committee shall be addressed to the Commission, in particular to the Directorate-General for the Environment, Nuclear Safety and Civil Protection, for unless the Member States are otherwise advised by the Commission.

11.2 Any correspondence for the representative of the Member States and the Committee shall be addressed to the Permanent Representations; copies of documents shall be sent directly and simultaneously to a limited number of officials appointed by these Member States, provided the Member States have notified the Commission of the names and addresses of these officials.

Article 12

12.1 In conformity with Article 214 of the Treaty, and without prejudice to Article 19 of Directive 90/219/EEC, the deliberations of the Committee shall be of a confidential nature.

Adopted in Brussels on 5 July 1991

RECYCLED PAPER

More information can be obtained from the Commission of the EC.

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