COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 4 May 1988

Proposal for a
COUNCIL DIRECTIVE

on the contained use of genetically modified microorganisms

Proposal for a
COUNCIL DIRECTIVE

on the deliberate release to the environment of genetically modified organisms

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(submitted by the Commission)

PROPOSAL

FOR A

COUNCIL DIRECTIVE ON THE CONTAINED USE OF GENETICALLY MODIFIED MICROORGANISMS

EXPLANATORY MEMORANDUM

I. INTRODUCTION

1. In its Communication to the Council "A Community Framework for the Regulation of Biotechnology" (Com(86)573 final), the Commission signaled its intention to introduce proposals for Community Regulation of biotechnology which would address two distinct aspects of the use of genetic engineering:

A. Levels of physical and biological containment, accident control and waste management in industrial applications;

B. Authorization of planned release of genetically modified organisms to the environment.

2. The detailed rules for the containment of genetically modified microorganisms which are pathogenic to humans are laid down in the proposal for a Council Directive on the protection of workers from the risks related to exposure to biological agents at work. These rules have worker protection as their primary objective and are complementary to the proposals on contained use of genetically modified microorganisms accompanying this memorandum.

3. A further proposal deals with the release of genetically modified organisms to the environment, and together with this proposal and the worker protection proposal forms a coherent legal framework to deal with questions of genetically modified organisms.

4. It is obviously necessary that installations carrying out work with genetically modified microorganisms do this in a manner which presents or minimizes any potential risk to man and the environment and while it is recognized that in the majority of cases the microorganisms used will constitute a minimal risk and require only that good operating practices are respected, there will be other cases where by virtue of the presumed pathogenicity or other properties of the microorganism in question, special measures for containment and, if necessary, accident response procedures will be appropriate. Therefore, regulatory measures are needed to ensure that the use of genetically modified microorganisms is undertaken with the degree of security (control) commensurate with the potential risk involved.

5. In 1986, the OECD Council issued a Recommendation on safety considerations for applications of Recombinant DNA. The Commission and the Member States participated in the preparation of this Recommendation.

The technical control of the Commission's proposals are based on this OECD Recommendation.

6. As the development and industrial application of the new techniques of genetic engineering continue to expand very rapidly the Commission considers that, both from the viewpoint of avoiding the fragmentation of the market and of ensuring a high and consistent standard of protection for man and the environment, regulatory measures should be introduced at a Community level in relation to the contained use of genetically modified microorganisms.

II. THE CONTAINED USE OF GENETICALLY MODIFIED MICROORGANISMS

1. LEGISLATION IN THE MEMBER STATES OF THE EUROPEAN COMMUNITIES

Several Member States have been reviewing existing regulations and some have issued specific rules concerning the contained use of biotechnology.

In Belgium a 'rDNA Advisory Committee' is in creation, in order to channel biotechnology-related issues to the competent authorities. There is no specific regulation in the field of biotechnology but it is estimated that a number of existing rules would apply. These include systems of authorizations for production, and for liquid and solid waste transport and disposal as well as legislation on worker protection.

In Denmark the Folketing adopted in May 1986 a bill on 'Environment and Gene Technology'. Concerning workers' safety an order on "Gene Technology and Working Environment" was issued in September 1987. Research can be carried out only in laboratories classified for the purpose by the National Labour Inspection, and each experiment has to be notified and registered. Production in industry must be previously licenced by the competent authorities. This involves the review of a risk assessment study and the approval of the containment and emergency measures proposed by the applicant.

In the Federal Republic of Germany the contained use of genetically modified microorganisms is subject to several provisions. Research activities are subject to guidelines; the disposal of liquid wastes from production and utilization of genetically modified microorganisms are subject to authorization, as is the establishment and functioning of industrial installations producing medicinal products or their intermediates using biotechnology.
Moreover the Association (Berufsgenossenschaft) of the chemical industry has prepared a recommendation for accident prevention in laboratories and industrial installations using biotechnologies. The Minister for Social Affairs has given his agreement and the different associations will now implement these recommendations in their own sector.

In France there are guidelines for research with genetic technologies which provides for voluntary notification of certain high risk projects to a scientific committee (Commission de Classement). Industrial activities using genetically modified microorganisms are subject to the Law on 'Classified Installations for Environmental Protection' and at present must be authorized before beginning to work. An interdepartmental working group, meeting by initiative of the Prime Minister, is evaluating whether industrial activities should be distinguished on the basis of the microorganism used and submitted to declaration when using low risk microorganisms.

Greece has set up an interdepartmental Committee, the 'Ad-Hoc Committee on Biohazards' which is responsible for the coordination of biosafety activities in relation to research projects.

In Ireland a statutory Recombinant DNA Committee has been set up to receive and examine notifications for research projects falling within categories of high risk. The Committee also receives proposals for industrial large scale work and issues case by case recommendations to the local authorities on conditions to be met regarding the plant's design, the containment measures and the safety of workers.

In Italy, Spain and Portugal no specific guidelines or rules apply to the contained use of biotechnology; however, a number of existing regulations related to products are applicable.

In Luxembourg there are no specific laws with respect to biotechnology. At present, both laboratories and industrial installations using genetic technologies fall under the general rules for 'Classified Installations' where authorization is needed before beginning to work.

In the Netherlands guidelines have been set up for research and industrial production. Also, genetically manipulated microorganisms are regulated under the Nuisance Act which requires a licence for hazardous installations. The licence could specify the provisions to be adopted for containment and emergency response. The licence is given by the Community Council and is normally based on advice of the Recombinant DNA Committee.

In the United Kingdom the general requirements of the Health and Safety at Work Act and the Genetic Manipulation Regulations, issued under this Act, apply to researchers and industries using genetic technologies. Notification of activities is required, and Guidelines on Safe Work are issued by the Advisory Committee on Genetic Manipulation, while the Health and Safety Executive inspectors carry out active controls for enforcement. The Health and Safety Commission is planning to propose statutory notification for the large scale use and planned release of genetically modified microorganisms, because at present such notifications are on a voluntary basis.

2. COMMENTS ON THIS PROPOSAL FOR A DIRECTIVE

A. General

This proposal deals with the contained use of genetically modified microorganisms including questions of waste and accident prevention. While some naturally occurring microorganisms may also be of concern in that they may present dangers to plants, animals or the environment in general, the Commission considers that in the first instance priority should be given to a legal framework which will both provide adequate protection and at the same time allow society to benefit from this rapidly evolving technology.

The Commission is however working towards the development of coherent methods of risk assessment in this field and will on this basis examine if and how the accompanying proposal could be modified or extended to cover non-genetically modified microorganisms.

Genetically modified microorganisms can be released to the environment in the course of their contained use in two different ways:

- routine release in normal operating conditions e.g. as wastes or in airborne emissions,
- accidental release in abnormal operating conditions i.e. significant release in the environment following an event which causes the activity to get out of control.

In certain cases such releases will pose risks to human health and the environment; it is therefore necessary to:

1) Identify these cases,
2) Adopt working practices and containment measures corresponding to the hazard the microorganism represents,
3) Prevent the accidental release of hazardous microorganisms and limit the consequences of any such accident which may occur.

This proposal for a directive covers the steps from 1 to 3.

For the purpose of this directive genetically modified microorganisms are divided in two groups:

microorganisms presenting a minimal hazard (Group I) to which relatively simple rules of good hygiene and safety practice shall be applied, and other microorganisms (Group II) where containment, waste control and in some cases emergency response procedures are essential.

In all cases users have to declare the fact that they are carrying out operations involving genetically manipulated microorganisms to the responsible authorities and carry out a hazard assessment.

A system of notification to the competent authority is then established, to allow effective monitoring and control of the correctness of the classification and of the containment measures applied.

The time schedule and the content of the notification is dependent upon the classification of the microorganism and on the scale of the operation involved. In respect of the latter the Commission considers more appropriate to adopt a flexible approach and distinguish the activities on the basis of their purpose. 'Industrial scale operations' would include manufacturing processes, and pilot plants whereas 'non-industrial scale operations' would include teaching, research and development activities.

In order to ensure that the probability of accidental release is reduced to a minimum, the proposal envisages special provisions in such cases of higher risk or incertitude. These are represented by the industrial scale operations using microorganisms belonging to group II. The notification in this case will be more detailed and the user will prove that he has studied possible causes of accidents, anticipating the combination of events which might lead to an unintended release and adopted safety measures and emergency response plans where appropriate. The user must also forward to the competent authority the information necessary to set up an emergency plan for the area surrounding the installation, should an accident occur.

In addition, the proposal for a Directive provides for the competent authorities to be notified of accidental releases occurring in their territory and for an effective preventive and monitoring system to be set up at Community level.

General provisions are made for the adapting of the directive to technical progress.

Technical annexes laying down containement and waste measures are largely drawn from the OECD Recommendation.

B. Particular comments on certain articles of the proposed Directive

ARTICLE 1

The definition of 'microorganism' is intended to cover microscopic living entities, cellular or non cellular, with capacity of self perpetuation. Microorganisms can be viruses, prokaryotes (for example, bacteria) eucaryotes (for example, fungi) or protista. This definition includes mammalian and plant cell cultures.

The definition of 'genetically modified microorganism' is intended to be broad so as to include present and future techniques. It excludes deletion, mutagenesis, conjugation, transformation, transduction or any other process if they are carried under normal physiological conditions and do not involve the use of recombinant DNA techniques or genetically modified organisms.

The definition of contained use relies upon the degree to which both physical and biological methods are used to control or restrict dissemination of microorganisms. For this purpose 'biological barriers'are those characteristics the microorganisms possess which limit their ability to survive. 'Physical and chemical barriers' consist of a set of equipment, operating procedures and practices and facility design which restrict dissemination of the microorganism into the unrestricted environment. This approach is purposely flexible: there are a large number of combinations of biological, physical and chemical barriers that could be deployed to prevent release into the environment.

ARTICLE 2, ARTICLE 4 AND ARTICLE 5

These articles represent the general provision of the proposed Directive. Article 2 sets out the criteria for the classification of genetically manipulated microorganisms, Article 4 the obligation to carry out a prior safety assessment of the operation and to keep it under review, Article 5 establishes the containment measures to be applied for each group of microorganism.

ARTICLE 6

This article provides for an initial declaration to be forwarded by all persons wishing to work with genetically modified microorganisms. Each declaration will refer to a particular installation or building. A 60 day waiting period is established in order to allow the competent authority receiving the declaration to carry out effective inspection of the installation concerned and enforce the specific duties placed on the users under this proposed Directive. This declaration, requiring a minimum set of particulars (listed in Annex IV A) will enable the competent authority to know at least where the contained uses are being undertaken.

ARTICLE 7

This article establishes the requirements for users of microorganisms from Group I according to the scale of use:
- non-industrial scale operations: record of work must be available upon request of the competent authority;
- industrial scale operations: prior notification of the information listed in Annex IV.B, work can proceed immediately.

ARTICLE 8

This Article establishes the requirements for users of microorganisms from Group II according to the scale of use:
- non-industrial scale operations: prior notification of the information listed in Annex IV.C with a 15 days waiting period;
- industrial scale operations: prior notification of the information listed in Annex IV.D with a 60 days waiting period.

ARTICLE 9

This article establishes the requirements for the updating of the notification where the users shall inform the competent authority as soon as possible of all information or modifications which could affect the notification already made. This would include a change in the microorganism or in the techniques used or in the number of personnel involved in the operation, thus enabling the competent authority to be informed of all ending activities.

ARTICLE 10 and ARTICLE 11

These articles specify the responsibilities of the competent authorities who shall receive the declarations and the notifications. In particular they will examine the notification, carry out inspections and checks, and take all requisite measures with a view of preventing accidents or limit the consequences of such accidents, including drawing up of external emergency plans.

ARTICLE 12

This article concerns the information which the users must give to the competent authority in the event of an accident and the consequent action that shall be taken by the latter.

ARTICLE 13

This article specifies the information which the Member States are to send to the Commission: extracts from the notifications concerning industrial scale operations with Group II microorganism and information about accidents occurring. This article also provides for the organization of exchange of information and the setting up of a data base to which the Member States are to have access.

ANNEX I and ANNEX II

These annexes provide the criteria whch must be followed in classifying a genetically manipulated microorganism and in assessing the risks for human health and the environment which may be entailed by its contained use. Both these annexes are based on the principles outlined in the OECD Report cited in I.5.

In both these annexes, unless it is differently specified, the definition of pathogen applying is the same as that outlined in the OECD report i.e.:

Pathogenicity is the potential ability of living organisms and viruses to cause disease in man, animals an plants.

PROPOSAL

FOR A

COUNCIL DIRECTIVE ON THE CONTAINED USE OF GENETICALLY MODIFIED MICROORGANISMS.

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community and in particular Article 100 A therof,

Having regard to the proposal of 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 disparity between the regulation of the contained use of genetically modified microorganisms which are in effect or in preparation in the Member States may create unequal conditions of competition, whereas these distortive effects are specifically important in areas where technical progress of the undertakings involved largely depend on the conditions under which the operation concerned may legally be carried out, whereas disparities of these conditions in the Member States thus directly affect the functioning of the internal market;

Whereas measures for the approximation of the provisions of the Member States which have as their object the establishment and functioning of the internal market shall, inasmuch as they concern health, safety, environmental and consumer protection, take a high level of protection as a base and provide, despite existing differencies in economies of the Member States, for equal standard of protection throughout the Community;

Whereas under the Treaty, action by the Community relating to the environment shall be based on the principle that preventive action shall be taken;

Whereas the Fourth Environmental Action Programme of 19 October 1987 (4) of the European Communities declares that measures concerning the evaluation and best use of biotechnology with regard to the environment are a priority area where 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 microorganisms will be used in industrial and non-industrial scale operations;

Whereas microorganisms, whether released in the environment as air emission, liquid or solid wastes or by accident in the course of their contained use may reproduce and spread crossing national frontiers thereby affecting bordering Member States or the Community as a whole;

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(1)
(2)
(3)
(4) O.J. N° C 328, 7.12.87, p.1.

Whereas the contained use of genetically modified microorganisms must be carried out in such way as to limit their negative consequences for the health of the general population and the environment giving due attention to the prevention of accidents and the control of wastes;

Whereas it is therefore necessary to approximate legislation in the Member States establishing a common procedure for the evaluation of the potential risks arising in the course of the contained use of genetically modified microorganisms in research, development, manufacture, storage, transport, waste treatment and disposal in order to enable the safe development of biotechnology throughout the Community;

Whereas the precise nature and scale of risks associated with genetically modified microorganisms are conjectual and the hazards involved must be assessed case by case, whereas particular attention must be given to operations using certain genetically modified microorganisms;

Whereas genetically modified microorganisms must be classified in relation to their hazard, whereas in the absence, at the moment, of specifications necessary for allocation of these classes it seems appropriate to provide criteria for classification, whereas to evaluate hazard for human health and the environment it is necessary to enumerate certain characteristics of the assessment;

Whereas the possible accidents should be obviated at source by the integration of containment measures at the various stages of development, construction and operation;

Whereas a permanent inventory within each Member State is necessary in order to follow closely the development of the contained use of genetically modified microorganisms and to trace the origin of any deleterious effect that might arise;

Whereas any person, before undertaking for the first time the contained use of a genetically modified microorganism must forward to the competent authority a declaration of intent allowing the authority to ensure that the proposed activity does not present a danger to man and the environment;

Whereas, in the case of industrial operations involving certain genetically modified microorganisms it is necessary for the user to provide the competent authorities with information including details of the microorganism used, the installation and the operation in question, with a view to reducing the hazards of accidental release and enabling the necessary steps to be taken to reduce their consequences;

Whereas it is necessary to lay down that any person outside the installation liable to be affected by an accident should be appropriately and effectively informed on all matters relating to safety, whereas area and persons liable to be affected are defined by the emergency plans of the industrial operation; whereas, in order to mitigate the consequences of an accidental release the information on potential hazards and measures to be taken has to be communicated on an active basis to the concerned persons without a request being made, though some kind of public information media, such as leaflets of information boards;

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

Whereas a continual analysis of the situation throughout the Community must be undertaken in order to promote both the establishment of lists of activities which ought to be subject to special safety measures or the imposition of more stringent containment measures, whereas in order to enable this analysis the Member States should forward to the Commission information regarding certain industrial scale operations with genetically modified microorganisms and the accidental releases occcurring in their territory,

HAS ADOPTED THIS DIRECTIVE:

ARTICLE 1

1. For the purposes of this Directive:

(a) "Microorganism" means any microbiological entity, cellular or non-cellular, capable of replication.

(b) "Genetically modified organism" means any organism derived from the formation of a new combination of genetic material by the insertion of nucleic acid molecules produced by whatever means outside the cell, into any virus, bacterial plasmid or other vector system so as to allow their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation.

(c) "A contained use" is any operation in which microorganisms are genetically modified, cultured, stored, transported, destroyed or disposed of and for which physical, chemical or biological barriers are used to limit their contact with people and the environment. It does not include operations with microorganisms to be released in the environment under Council Directive ... (deliberate release) or products to be placed on the market under relevant EC legislation.

(d) "Industrial scale operation" is any contained use carried out as part of a manufacturing process, including uses at the pilot plant stage for the development of such processes.

(e) "Non-industrial scale operation" is any other contained use including for teaching, research and development purposes.

(f) "Accident" means: any incident involving significant and unintended emission of genetically modified microorganism in the course of their contained use that leads to a serious danger, immediate or delayed, to the health of the general population or the environment.

(g) "User" means: any natural or legal person responsible for the contained use of genetically modified microorganisms.

(h) "Notification" means: the presentation of documents containing the requisite information to the competent authority of a Member State.

ARTICLE 2

1. For the purpose of this Directive, genetically modified microorganisms are classifed as follows:

Group I: Those satisfying the criteria of Annex I
Group II: Those other than Group I

2. For non-industrial scale operations, the classification by the user of particular microorganisms may be provisional. In this case microorganisms will be referred to as 'equivalent' to the above groups.

ARTICLE 3

1. This Directive shall apply without prejudice to the provisions of Council Directive ... on the protection of workers from the risks related to exposure to biological agents at work.

2. Articles 5 to 10 do not apply to the transport of genetically modified microorganisms on public roads, rail, inland waterway, sea or by air.

ARTICLE 4

1. The Member States shall take the necessary steps to ensure that the contained use of genetically modified microorganisms shall be carried out in such a way as to prevent their negative consequences for the health of the general population and the environment.

2. To this end, the user shall carry out a prior assessment of the contained uses in respect of the biological hazards that they may incur.

3. In making such an assessment the user shall, in particular, take due account of the relevant parameters set out in Annex II for any genetically modified microorganism he is proposing to use.

4. A record of the safety assessment shall be kept by the user and made available to the competent authority upon request.

ARTICLE 5

1. For microorganisms in Group I the principles of Good Microbiological Practice as laid out in Council Directive 80/1107/EEC shall be applied.

2. In addition to these principles, the containment measures set out in Annex III shall be applied, as appropriate, to contained uses of microorganisms in Group II so as to ensure a high level of safety.

3. The containment measures applied shall be periodically reviewed to take into account new scientific or technical knowledge relative to risk management and waste disposal.

ARTICLE 6

Any person wishing to undertake for the first time in a particular installation the contained use of genetically modified microorganisms shall be required to submit to the competent authority, at least 60 days before commencing such use, a declaration containing at least the information listed in Annex IV.A.

ARTICLE 7

1. Users of microorganisms classified in, or equivalent to, Group I in non-industrial scale operations shall be required to keep records of the work carried out which shall be available to the competent authority on request.

2. Users of microorganisms classified in Group I in industrial scale operations shall be required to submit to the competent authority, before commencing such use, a notification containing the information listed in Annex IV.B. The information shall be sufficient to enable the competent authority to assess the correctness of the classification. After submission of the notification the industrial scale operation can proceed.

ARTICLE 8

1. Users of microorganisms classified in or equivalent to Group II in non-industrial scale operations shall be required to submit to the competent authority, before commencing such use, a notification containing the information listed in Annex IV.C. The contained use may, in absence of any indication to the contrary from the competent authority, proceed 15 days after submission of the notification.

2. Users of microorganisms classified in Group II in industrial scale operations shall be required to submit to the competent authority before commencing such use, a notification containing:

- Information about the microorganism(s),
- Information about personnel,
- Information about the installation,
- Information about waste management,
- Information about accident prevention and emergency response plans,
- The safety assessment referred to in Article 4,

the details of which are listed in Annex IV.D.

The contained use may, in 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.

ARTICLE 9

The competent authority shall be informed as soon as possible and the declaration and the notification under Articles 6, 7 and 8 shall be modified, when the user becomes aware of new information or modifies the contained use in a way that could have significant consequences for the risk posed by the contained use, or which affects the contents of the original declaration and notification.

ARTICLE 10

1. Member States shall designate the competent authority or authorities who shall ensure that this Directive is correctly applied and shall receive the declaration and the notifications referred to in Articles 6, 7 and 8.

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

3. If necessary, the competent authority may ask the user to provide further information or to introduce modifications to the conditions of the proposed contained use.

4. In this case the relevant waiting period is extended until the notifier complies with the request of the competent authority and has informed them thereof.

ARTICLE 11

The competent authority is also responsible for:

- organizing inspections and other control measures to ensure the user's compliance with this Directive,

- Ensuring that,where necessary, before an operation commences an emergency plan is drawn up to deal with biological hazards outside the installation in the event of an accident and that the emergency services are aware of the hazards and are informed of such in writing,

- Ensuring that all persons liable to be affected by an accident are informed in an appropriate manner of the emergency response measures and of the correct behaviour to adopt, sending to the other Member States concerned the same information as that which is disseminated to their own nationals. The information shall be commmunicated to the above mentioned persons without their request and shall also be published.

ARTICLE 12

1. Member States shall take the necessary measures to ensure that, if an accident occurs which can endanger the health of the general population and the environment, the user shall be required to immediately inform the competent authority specified in Article 10 and provide the following information:

- the circumstances of the accident,
- the identity and quantities of the microorganism(s) released
- any information necessary for the assessment of the effects of the accident on the health of the general population and the environment,
- the emergency measures taken.

2. The Member States shall:

- ensure that any emergency, medium and long-term measures which may prove 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 make recommendations for the avoidance and the limitation of the effects of similar accidents in the future.

ARTICLE 13

1. Member States shall:

a) ensure that in the case of contained uses notified under Article 8.2, the competent authority sends the following information to the Commission within 60 days of receipt of the notification:

- the identity, proposed uses and potential risks of the microorganism(s),
- a summary of the containment measures applied,
- a summary of the emergency plans referred to in Article 11.

b) consult with other Member States likely to be affected in case of an accident in the drawing up and implementation of emergency plans.

c) 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 microorganisms released, the emergency response measures employed and their effectiveness, and an analysis of the accident including recommendations for the limitation of its effects and the avoidance of similar accidents in the future.

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

ARTICLE 14

1. Every three years, Member States shall send the Commission a summary report on their experience with this Directive, the first time being on 1st September 1991.

2. Every three years, the Commission shall publish a summary based on the report referred to in paragraph 1, the first time being in 1992.

3. 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 substantial harm to the competitive position of a user.

ARTICLE 15

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

2. Amendments made to the annexes of this Directive to adapt them to technical progress shall be adopted by the Commission in accordance with the procedure laid down in Article 16.

ARTICLE 16

Where the procedure laid down in this Article is followed, 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, if necessary by taking a vote. The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes. The Commission shall take the utmost account of the opinion delivered by the Committee. It shall inform the Committee of the manner in which its opinion has been taken into account.

ARTICLE 17

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

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

ARTICLE 18

This Directive is addressed to the Member States.

ANNEX I

CRITERIA FOR CLASSIFYING GENETICALLY MANIPULATED MICROORGANISMS IN GROUP I

Host or parental organism

- Non-pathogenic,
- No adventitious agents,
- Proven history of extensive safe use or
- Built-in environmental limitations permitting optimal growth in the reactor or fermenter but limited survival without adverse consequences in environment.

Vector/Insert

- Well characterised and free from Known harmful sequences,
- Limited in size as much as possible to the DNA 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 mobilisable,
- Should not transfer any resistance markers to microorganisms not known to acquire them naturally (if such acquisition could compromise use of drug to control disease agents).

Genetically manipulated microorganism

- Non-pathogenic,
- As safe in the reactor or fermenter as host or parental organism, but with limited survival without adverse consequences in the enviroment.

Other classes of microorganisms that could be included in Group I if they are not pathogenic are:

- those constructed entirely from a single prokaryotic host (including its indegenous plasmids and viruses) or from a single eukariotic host (including its chloroplasts, mitochondria, plasmids, but excluding viruses),

- those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes.

ANNEX II

Points to consider in conducting the safety assessment referred to in Article 4.

A. Characteristics of the parental microorganism(s)
B. Characteristics of the modified microorganism
C. Health considerations
D. Environmental considerations

A. Characteristics of the parental microorganism(s)

- Names and designation,
- Degree of relatedness,
- Sources of the microorganism(s)
- Information on reproductive cycles (sexual/asexual) of the parental microorganism(s) or, where applicable, of the host microorganism,
- History of prior genetic manipulations,
- Stability of parental or of recipient microorganism in term of relevant genetic traits,
- Nature of pathogenicity and virulence, infectivity, toxicity and vectors,
- 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,
- Interaction with and effects on other organisms in the environment,
- Ability to form survival structures.

B. Characteristics of the modified microorganism

- The nature of the modification,
- the function of the genetic manipulation 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 microorganism,
- Stability of the microorganism in term of genetic traits,
- Frequency of mobilisation of inserted vector and/or genetic transfer capability,
- Rate and level of expression of the new genetic material,
- Activity of the expressed protein.

C. Health considerations

- Allergenic and toxic hazard of the protein or of non-viable microorganism,
- Comparison of the modified microorganism to the parent microorganism regarding pathogenicity,
- Capacity for colonisation,

- If the microorganism 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) Availibity of appropriate therapies.

D. Environmental considerations

- Factors affecting survival and multiplication of the engineered microorganism in the environment,
- Available techniques for detection, identification and monitoring of the engineered microorganism,
- Available techniques for detecting transfer of the new genetic material to other organisms,
- Known and predicted habitats of the engineered microorganism,
- Description of ecosystems to which the microorganism could be accidentally disseminated,
- Anticipated mechanism and result of interaction between the engineered microorganism and the organisms or microorganisms which might be exposed in case of release to the environment,
- Known or predicted effects on plants and animals such as pathogenicity, infectivity, toxicity, virulence, vector of pathogen, allergenicity, colonisation,
- Known or predicted involvement in biogeochemical processes,
- Availability of methods for decontamination of the area in case of release to the environment.

ANNEX III

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

Industrial uses 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.

Containment measures for non-industrial scale operations shall be derived from the containment categories below, bearing in mind the specific circumstances of smaller-scale operations.

SPECIFICATIONS	CONTAINMENT CATEGORIES 1	2	3
1. Viable microorganisms should in a system which physically separates the process from the environment (closed system)	yes	yes	yes
2. Exhausted gases from the closed system should be treated so as to:	Minimise release	Prevent release	Prevent release
3. Sample collection, addition of materials to a closed system and transfer of viable microorganisms to another closed system, should be performed so as to:	Minimise release	Prevent release	Prevent release
4. Bulk culture fluids should not be removed from the closed system unless the viable microorganisms have been:	Inactived by validated means	Inactived by validated chemical or physical means	Inactived by validated chemical or physical means
5. Seals should be designed so as to:	Minimise release	Prevent release	Prevent release

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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 inactived before release	No	Optional	Yes
g) The controlled area should be adequately ventilated to minimise air contamination	Optional	Optional	Yes
h) The controlled area 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	No	Optional	Yes
k) The controlled area should be sealable to permit fumigation	No	Optional	Yes
7. Effluent treatment before final discharge	Inactived by validated means	Inactived by validated chemical or physical means	Inactived by validated physical means

ANNEX IV

PART A - Information required for the declaration referred to in Article 6

- name of person(s) responsible for carrying out the contained use;
- description of the education and training received by the persons who will carry out the work, of the persons who will take part in them, of the persons who will be responsible for supervision, monitoring and safety and of the person responsible for carrying out the safety assessment;
- the address of the installation;
- a description of the nature of the work which will be undertaken and in particular the classification of the microorganism(s) to be used and the likely scale of the operation.

PART B - Information required for the notification referred to in Article 7.2

- the date of submission of the declaration referred to in Article 6;
- the parental microorganism(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)
- the purpose of the contained use including the expected results;
- the culture volumes to be used.

PART C - Information required for the notification referred to in Article 8.1

- the information required in Part B
- description of the sections of the installation, 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 safety precautions and containment measures to be adopted including waste treatment provisions.

PART D - Information required for the notification referred to in Article 8.2

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 declaration referred to in Article 6 and the name of the responsible person(s)

b) information about the microorganism(s):

- the identity and characteristics of the microorganism(s),
- the purpose of the contained use or the nature of the product;
- the host-vector system to be used (where applicable);
- the volumes to be used;
- behaviour and characteristics of the microorganism(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 microorganism(s) to the environment;
- substances which are or may be produced in the course of the use of the microorganism(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 microorganism(s).

d) information about the installation:

- the activity in which the microorganism(s) is to be used;
- the technological processes used,
- a description of the sections of the installation,
- the predominant meteorological conditions, and sources of danger 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 microorganism(s),
- waste management techniques used, including recovery, liquid or solid wastes,
- 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 11

g) a comprehensive assessment (referred to in Article 4) of the potential hazards and risks which might arise from the proposed contained use.

PROPOSAL

FOR A

PROPOSAL FOR A COUNCIL DIRECTIVE ON THE DELIBERATE RELEASE TO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS

EXPLANATORY MEMORANDUM

I. INTRODUCTION

In its Communication to the Council "A Community Framework for the Regulation of biotechnology" (Com(86)573 final), the Commission signaled its intention to introduce proposals for Community Regulation of biotechnology which would address two distinct aspects of the use of genetic engineering:

A. Levels of physical and biological containment, accident control and waste management in industrial applications;

B. Authorization of planned release of genetically engineered organisms into the environment.

The current proposal concerns the release into the environment (aspect B). Industrial applications (aspect A) will be the subject of separate proposals.

The deliberate release into the environment of genetically modified organisms (GMOs) has given rise to particularly intense debate about the possible risks involved. The application of these organisms in the open environment is very broad: pesticides, herbicides, nitrogen fixation (in microorganisms or in crop-plants), plants and animals resistant to pests and diseases, adapted to extreme meteorological conditions or scarcity of resources, degradation of toxic chemicals and oil spills, enhanced oil recovery, metal leaching of low-grade ores, and many others.

At the same time, however, the intentional release of organisms having a combination of traits that nature may have never produced increases uncertainty as regards the behaviour of the organism and the possibility of a deleterious impact on the environment. Not only known or predicted traits of the organism (such as pathogeniticy, etc.) may raise questions but also the possibility of displacement of natural populations, alteration of ecological cycles and interactions, and undesired transference of novel genetic traits to other species (i.e., pesticide-resistance of a crop-plant passed on to weeds). This makes it necessary to proceed with the releases in a careful manner. Therefore, regulatory measures are needed to ensure that these releases be carried out only under conditions of human and environmental safety which are as high as reasonably practicable.

It must also be adknowledged that the use of GMOs could lead to improvements in helath and the environment by permitting the development of more precise agricultural inputs for protection and nutrition and more effective treatment of waste.

A recent OECD report ("Recombinant DNA safety considerations",1986) recognized the risks mentioned above and concluded that they can be assessed, to some extent, by analogy with information about existing organisms. However, there is insufficient experience at this stage provide a basis for coherent standards for testing and regulations. Instead, the Report recommends a prior case-by-case evaluation of all deliberate releases.

The Commission believes that the rapid elaboration of a Community framework of biotechnolgy regulation is of crucial importance to the development of this new technology in the Community. Citizens and the environment throughout the Community need to be provided with adequate protection from any potential hazards arising from the application of genetic engineering. The internal market arguments for Community-wide regulation in this field are clear and, from an environmental viewpoint, organisms are no respecters of national frontiers, and nothing short of Community-wide regulation can offer the necessary human and environmental protection.

Because international experience in deliberate release is still limited, it is not possible to propose any general guidelines or testing requirements for the time being. The Commission is therefore proposing a case-by-case notification-and-endorsement procedure which will be mandatory for industry and research institutions, in line with the recommendation of the OECD report.

II. LEGISLATIION IN THE MEMBER STATES OF THE EUROPEAN COMMUNITY

Several Member States have been reviewing existing regulations and generally assessing the risks to humans and the environment from the release of genetically engineered organisms.

In the Federal Republic of Germany a general ban on the deliberate release of genetically modified organisms (GMOs) has been established. Exemptions are on a case-by-case basis, without any formal authorization procedures. The German authorities are currently deciding whether a legal framework is neceesary to regulate the deliberate release of GMOs, taking into account a recent Bundestag report on the subject.

In Italy, no specific regulation applies to the deliberate release of GMOs. A first proposal for release is being examined under pesticide legislation.

In The Netherlands, regulations for environmental release are in preparation. At present, there is no ban on the release of GMOs; the Government allows experiments to proceed where adequate review has been provided.

In France, the Ministry of Agriculture has established a commission (Commission de Génie Biomoléculaire) to examine case-by-case the deliberate release of GMOs.

Belgium is covering GMOs under existing legislation, having gained some experience with a proposed release of genetically modified potato plants.

Luxembourg is examining closely the deliberate release of GMOs. The possibility of ad hoc authorizations will be examined by the Ministry of the Environment.

In the United Kingdom, guidelines for the deliberate relase of GMOs were approved in April 1986. These guidelines, prepared by the Advisory Committee on Genetic Manipulation (ACGM) establish a framework for the case-by-case consideration of proposals by an expert national body and relevant governmental departments, and has set up a sub-committee to oversee individual notifications. This scheme is at present voluntary, but the ACGM has proposed statutory notification for deliberate releases.

The guidelines, which will apply to organisms obtained through genetic manipulation, will cover releases to the environment in large scale and field trials under non-contained conditions. It is envisaged that when GMOs developed for release have been fully assessed by ACGM, HSE and other relevant governemental departments, routine use will be exempt from the notification procedure.

In Denmark, the Danish Folketing adopted in May 1986 a bill on genetic engineering and other technologies, including agricultural and environmental uses of GMOs and products containing them. The provisions of the law state:

- release of GMOS may not take place even for research purposes; the Ministry of the Environment may approve such releases in special cases;

- applicant in these cases must, if so required by the Authorities, provide information and test results in accordance with certain guidelines and at certain laboratories. The Ministry of the Environment may lay down detailed rules on the implementations of the approval arrangements;

The law covers:

- inspection, information on accidents, prohibition after authorization has been granted, imported substances, local authorities and the possiblity of appeal against decisions taken under the law.

Ireland has set up a Recombinant DNA Committee and an Institutional Biosafety Committee. Deliberate releases will require review and approval by these Committees, which will follow the OECD recommendations. In addition, provisions of a number of Irish laws are relevant in the cases of deliberate releases, including the Water Pollution Act, the Dangerous Substances Act and the Destructive Insects and Pests Act.

In Greece, there are no specific regulations in this field, but an 'Ad hoc Committee of Biohazards' has been set up with responsibility in the coordination of biosafety activities.

In Spain, no specific regulations apply to deliberate release of GMOs, but a committee is being set up to be responsible of these activities

In Portugal, there are no specific regulations in the field but the Secretariat of State of Environment will be responsible for the subject.

COMMENTS ON THIS PROPOSAL FOR A DIRECTIVE

1.General

The possible hazards from the release to the environment of genetically modified organisms are of various types:

- pathogenicity to humans, animals or plants;
- disruptive effects on ecosystems : displacement of natural populations, alteration of ecological cycles and interactions;
- transfer of the novel genetic traits to other species with undesired effects;
- excessive dependence on species lacking genetic variation.

However, public concern about genetic engineering is growing, and it is easy to imagine the public's response in case of harm to people or the environment caused by a GMO deliberately introduced in the environment. Moreover, genetic engineering will sharply increase the number of organisms with new traits introduced in the environment. These reasons make it urgently necessary to provide protection to people and the environment from the possible risks related to these new techniques.

The present approach, which focusses on the new techniques of genetic engineering, is the first and most urgent step in the regulatory process; however, this will not impede evolution towards a more organism-related approach. Thus, the Commission will, as experience and knowledge on the matter build-up, undertake to regulate the release of certain categories of naturally-occuring organisms, such as known human, plant or animal pathogens, and non-indigenous organisms. Moreover, different categories of organisms and/or techniques may be established, allowing different requirements for organisms of different levels of risk.

This Directive will establish a case-by-case notification and endorsement procedure for the deliberate release of GMOs. Before carrying out a release, the person responsible for it shall submit a notification to the Competent Authority of his Member State, including a detailed risk assessment where the possible hazards associated with the release must be identified.

However, understanding that there is a clear quantitative difference in the level of risk between experimental releases (carried out under very controlled conditions, strictly limited in space and time, closely monitored) and commercial ones (with limitations only in areas and conditions of use), two different procedures will be established: one for experimental releases where each competent authority is fully responsible for the releases carried out in its Member State, and a second one for the placing on the market of genetically modified organisms for a given use, where consultation and agreement with the other Member States is needed before the product is endorsed for its placing on the market.

The endorsement procedure has the advantage over an authorization procedure, that it leaves responsibility with the notifier. Moreover, in a field largely unknown like this, the decisions as to the safety of a release and its conditions must be the result of a dialogue between notifier and Competent Authority.

In a largely unexplored field like this, the exchange of information is likely to play an essential role in gaining experience. Therefore, provision is made for information exchange among the Member States through the Commission. This information sharing will be without restriction for the Commission and the Competent Authorities, provided that absolute confidentiality is guaranteed for these data. The experience from the chemicals sector, where notification units for new chemical substances have been working for years with excellent results, encourages the Commission to pursue this goal.

On the other hand, given the public concern about genetic engineering, it is considered essential that the information necessary for evaluating the risk and adopting safety measures, be made available to the public.

2. Particular comments on certain articles of the Directive

The proposal is divided in four parts: Part A (articles 1 to 3) on general provisions, Part B (articles 4 to 7) on the deliberate release of GMOs for research and development purposes, Part C (articles 8 to 16) on the placing on the market of products containing or consisting of GMOs, Part D (articles 17 to 23) on final provisions.

PART A: GENERAL PROVISIONS

Article 2

The definition of "organism" encompasses viruses and other subcellular entities as well as higher plants and animals. It is understood that these organisms are living ones, including inactive forms such as seeds, spores, and the like.

Annex I, which will be updated as necessary, indicates the techniques by which the genetically modified organisms can be obtained.

"Deliberate release" is defined in opposition to "contained use". As the borderline between these concepts is not clear-cut, particularly in the case of greenhouses and stables (which can be considered contained or non-contained depending on the adoption of particular measures or on certain characteristics), and taking into account the need to establish clear criteria to trigger the notification under this Directive, the Commission will elaborate, in consultation with the Member states, guidelines for containment in greenhouses, stables and other facilities, which will clarify which activities will be considerd as deliberate release.

PART B: DELIBERATE RELEASES FOR EXPERIMENTAL PURPOSES

Article 4

This Article establishes the obligation to notify all releases in the research and development phase and outlines the content of the notification.

One of the most important features of the procedure of notification is that it promotes the dialogue between notifier and Competent Authority. This dialogue will serve to clarify all those cases where the application of the Directive is in doubt.

Article 5

This Article establishes that national Competent Authorities will be in charge of the review of the notifications and their endorsement. The Commission may establish regular contacts and interchanges among the different Competent Authorities, or carry out any other relevant activities in order to ensure a uniform and high-quality review by all Competent Authorities.

Article 6

This Article establishes the endorsement of a notification for an experimental release by the national Competent Authority. The Competent Authority, in order to endorse a notification, will have to be satisfied not only with the formal compliance of the dossier with the Directive but, above all, will have to consider the risk associated with the release acceptable.

Article 7

This article establishes the procedure for information exchange among Competent Authorites

PART C: PLACING ON THE MARKET OF PRODUCTS CONTAINING OR CONSISTING OF GMOs

Article 9 and 10

In these articles, the procedure for notification and endorsement for the placing on the market of products consisting of or containing GMOs is laid down. As these products must be able to circulate in the Community without trade barriers, provisions for consultation among Member States are considered, so that no product shall be endorsed without all Member States having had the right to object.

However, taking into account the high specificity expected for most of these products, and the diversity of environments within the Community, the endorsement is made valid only for the use of the product under very specific conditions and, where relevant, in specific geographical areas.

In cases where the experimental phase has demonstrated that the product to be notified is very safe, the notifier may ask not to comply with some notification requirements so as to simplify the endorsement of the product.

Article 12

This article establishes that products endorsed under this Directive must be commercialized under conditions which ensure their proper and safe use.

Article 13

This Article establishes the free circulation of products containing genetically modified organisms which have been properly endorsed.

Article 14

This is the safeguard clause, which allows Member Sates to impose provisional measures on the commercialization of products containing GMOs, until the Commission takes a Community-wide decision. The reasons for a national ban should in any case be scientific ones.

PART D: FINAL PROVISIONS

Article 17

This article establishes the right of the notifier to determine, to a certain extent, the information within the notification which is to be kept secret (except for the Commission and the Competent Authorities) in order to safeguard his competitive position. But, at the same time, it establishes a minimum set of data that, in any case, has to be made available to the public. This accounts for the citizen's right to information about potentially harmful activities, and will also help to promote public's confidence in the development of genetic engineering.

Article 18

This Article establishes the commitment to update the Directive to technical progress as necessary, given the rapid scientific development of this field.

Article 19

This article establishes the Committee which will advise the Commission in the application of the Article 14, the adaptation of the annexes to technical progress and the resolution of disputes before endorsement.

Annex I

This Annex is intended to provide, through a periodical update, as a clarification of what techniques can make an organism "genetically modified" within the meaning of this Directive. The techniques not covered are those that have long been used with crop plants and livestock with an excellent safety record.

Annex II

This Annex sets out the information requirements for the notification. It is not a checklist, for not all items are relevant in every case. Instead, it is intended as a comprehensive list of different aspects relevant for the evaluation of the risk, from which each notifier will pick those items which are relevant to their case.

The level of detail of the information to be provided and its quality will be a function of the type of release: a field test is likely to rely heavily on bibliographic data and assumptions, whereas a notification for a product should be based on experimental evidence. Competent Authorities will therefore examine the information requirements in a flexible manner.

Annex III

This Annex specifies the additional information required in the notification dossier in the case of the placing on the market of GMOs.

PROPOSAL

FOR A

COUNCIL DIRECTIVE ON THE DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty Establishing the European Economic Community and in particular Article 100A thereof,

Having regard to the proposal of 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, disparity between the regulation of the deliberate release to the environment of genetically modified organisms which are in effect or in preparation in the Member States may create unequal conditions of competition and thus directly affect the functioning of the common market; whereas, it is therefore necessary to approximate the laws of the Member States in this regard, as provided for in Article 100A of the Treaty;

Whereas measures for the approximation of the provisions of the Member States which have as their object the establishment and functioning of the internal market shall, inasmuch as they concern health, safety, environmental and consumer protection, take a high level of protection as a base (5) and provide, despite existing differences in economies of the Member States, for equal standards of protection throughout the Community;

Whereas under the Treaty, action by the Community relating to the environment shall be based on the principle that preventive action shall be taken, (4)

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(1)
(2)
(3)
(4)
(5)

Whereas living organisms, whether released to the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby affecting bordering Member States or the Community as a whole,

Whereas it is necessary to ensure the development of industrial products utilizing genetically modified organisms which do not cause harm to human health or the environment, whereas the new biotechnology promises improvements in health and the environment by developing more precise agricultural inputs for protection and nutrition and more effective treatment of wastes.

Whereas the protection of the public and the environment requires that due attention be given to controlling risks from the deliberate release of genetically modified organisms to the environment,

Whareas new techniqes of genetic modification are defined in Article 2.2 and Annex I of this Directive; whereas those techniques which have conventionally been used with crop plants and livestock with an excellent safety record are not covered by the definition of Article 2.2 or Annex I;

Whereas it is necessary to establish harmonized procedures for the evaluation of the potential risks arising from the intentional introduction, for the purpose of research and development, of gentically modified organisms into the environment,

Whereas, the deliberate release of genetically modified organisms at the research stage is in most cases a necessary step in the development of new products derived from or containing genetically modified organisms; and whereas the regulatory requirements under which these releases take place are likely to have important impacts on the final cost of such products;

Whereas it it necessary to establish a Community review and decisionmaking procedure for the placing on the market of the products containing or consisting of genetically modified organisms, where the intended use of that product involves its deliberate release to the environment,

Whereas any person, before undertaking a new deliberate release to the environment of a genetically modified organism, or the placing on the market of a product containing or consisting of genetically modified organisms where the intented use of that product involves its deliberate release to the environment, shall submit a notification to the national competent authority,

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

Whereas, it is important to follow closely the development and use of genetically modified organisms, and that in order to do this it is necessary to list all the products notified under this Directive, and to provide for subsequent notifications and follow-up information,

Whereas, when a product containing a genetically modified organism or a combination of them is placed on the market where the intended use of that product involves its deliberate release to the environment, and where such a product has been properly notified and endorsed under this Directive, a Member State may not prohibit, restrict or impede the deliberate release of this organism on their territory under the conditions set out in the notification, except under the specific conditions of a safeguard procedure, in case of a serious risk to human health or the environment;

HAS ADOPTED THIS DIRECTIVE:

PART A: GENERAL PROVISIONS

ARTICLE 1

1. The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect the health of the general population and the environment in relation with:

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

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

ARTICLE 2

For the purpose of this Directive:

1. Organism includes multicellular and unicellular organisms. It also includes subcellular entities capable of replication.

2. Genetically modified organism (hereinafter referred to as GMO) is an organism in which the genetic material is altered in a way that passes the natural barriers of mating and recombination. Annex I indicates the techniques by which such genetic alterations can be obtained.

3. Deliberate release means any intentional introduction in the environment of a GMO or a combination of GMOs without provisions for containment such as special procedures, equipment and installations, or facilities that provide physical barriers to prevent their spread into the environment.

4. Product means a preparation or formulation consisting of or containing a GMO or a combination of GMOs, which is placed on the market.

5. Placing on the market means supplying or making available to third parties for the purpose of sale or commercial distribution.

6. Notification means the documents whereby the person who is to carry out a deliberate release of a GMO or a combination or GMOs for the purpose of research and development, or to place a product on the market presents the requisite information to the competent authority of a Member State. This person shall be referred to as "the notifier"

7. Use means the deliberate release of a product which have been placed on the market. The persons carrying out this use will be referred to as "users".

ARTICLE 3

1. Member States shall adopt the provisions necessary to ensure that all persons carrying out the deliberate release or placing on the market of GMO(s) shall take all measures reasonably practicable to control any risk of harm to people and the environment.

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

PART B: DELIBERATE RELEASE OF GENETICALLY MODIFIED ORGANISMS TO THE ENVIRONMENT FOR RESEARCH AND DEVELOPMENT PURPOSES

ARTICLE 4

Member States shall adopt the provisions necessary to ensure that:

1. Any person, before undertaking a deliberate release of a GMO or a combination of GMOs for the purpose of research and development, must submit a notification to the competent authority specified in Article 3.2 of the Member State within whose territory the release is to take place before carrying out the release.

2. The notification shall include:

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

- identification and characteristics of the GMO(s),

- the location of the area where the deliberate release is to be carried out and the predominant meteorological, social, environmental and agricultural characteristics of the area,

- the purpose and conditions of the release, including the quantity of the GMO(s) to be released, the size of the area affected, and the duration of the release,

- all other information necessary for risk assessment,

- methods for monitoring the GMO(s) and, when appropriate, proposed techniques for elimination or inactivation of the GMO(s) at the end of the experiment, and for emergency response in case of the spread of the GMOs beyond the area of release.

b) A statement evaluating the impacts and risks posed by the GMOs to people or the environment from the uses envisaged.

3. The experimental release of a combination of different GMOs for the same purpose may be notified in a single notification.

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

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

6. In the event of any modification of the deliberate release of GMO(s) which could have consequences with regard to the risks for people or the environment or if new information has become available on such risks, either while the notification is being examined by the competent authorities or after the endorsement, the notifier shall:

   a) revise the measures specified in Article 4.2

   b) inform the competent authority of the modification, in advance or as soon as the new information is available, in so far as it affects the information contained in the notification.

ARTICLE 5

1. The competent authority shall:

   - evaluate the risk posed by the release in the light of the notifier's risk assessment,

   - state its conclusions in writing,

   and, if necessary,

   - ask the notifier to provide further information or verification tests, explaining the reasons for it,

   - carry out such tests as may be necessary for control purposes.

2. The competent authority shall respond to the notification within 90 days of its receipt, either deciding on its endorsement or indicating the further information required or measures to be taken.

3. If the competent authority is not satisfied with the conditions of the proposed release, it may ask the notifier to modify such conditions of the release so as to bring it into compliance with Article 3 of this Directive.

4. The notifier may proceed with the release only when he has received the endorsement of the competent authority, subject to any conditions required in this endorsement.

5. The Member States may provide for derogations from the provisions under articles 4 and 5.1 to 5.4 and 6 for deliberate releases carried out by or under the responsibility of a public authority which is designated as a competent authority according to articles 3.2. This derogation does not affect the obligation to assess the risk posed by the release concerned nor the obligation to submit information to the Commission as required in Article 7.

ARTICLE 6

On the completion of a release the notifier shall send to the competent authority an assessment of the result of the release in respect of any risk to man or the environment, with particular reference to any product that he intends to notify.

ARTICLE 7

1. The Commission shall set up a system of exchange of the information contained in the notifications. The competent authorities shall send to the Commission a summary of each notification received within 15 days of its receipt.

2. The Commission shall forward these summaries to the other Member States.

3. If a competent authority wants more information relative to releases carried out in other Member States, it may ask the competent authority of this Member State to provide them with further information.

4. The competent authority of the other Member States may suggest to the competent authority which received the original notification any modifications to the conditions of the release.

PART C: PLACING ON THE MARKET OF PRODUCTS CONTAINING GENETICALLY MODIFIED ORGANISMS

ARTICLE 8

Articles 9 to 16 of this Directive, do not apply to:

- medicinal products,
- veterinary products,
- foodstuffs, feedingstuffs and their additives,

- plants and animals produced or used in agriculture, horticulture, forestry, husbandry and fisheries, the reproductive material thereof and the products containing these organisms,
- or to any products covered by Community legislation which includes a specific risk assessment.

ARTICLE 9

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

   - the information required in Annex II, extended as necessary to take into account the diversity of sites of use of the product, and an assessment of any risks for man and/or the environment related to the GMO(s) contained in the product,

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

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

2. Subject to the agreement of the competent authority, the notifier may refer in this notification to data or experiences from releases of the same GMO(s) previously notified at the research and development level.

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

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

5. If new information has become available with regard to the risks of the product to people or the environment, either before or after the endorsement, the notifier shall:

   - revise the measures specified in Article 9.1, and

   - inform the competent authority immediately.

ARTICLE 10

1. On receipt of the notification referred to in Article 9, the competent authority shall examine it for compliance with this Directive, giving particular attention to the risk assessment and the recommended precautions related to the safe use of the product.

2. The competent authority may ask the notifier for additional information or suggest further tests to carry out or changes in the conditions of placing on the market so as to bring these conditions into compliance with the Directive.

3. When the competent authority is satisfied that the placing on the market of the product under the conditions specified in the notification is in compliance with this Directive, it shall send to the Commission a dossier including a summary of the notification together with a statement of the conditions under which it proposes to endorse the placing on the market of the product.

4. The competent authority shall respond to the notification within 90 days of receipt, either by indicating the need for further information and evaluation, or measures to bring it into compliance with this Directive, or forwarding the dossier referred to in Article 10.3 to the Commission.

ARTICLE 11

1. On receipt of the dossier referred to in Article 10, the Commission shall forward to all Member States:

   - the summary of the dossier,

   - any other information it has collected pursuant to this Directive.

2. For a period of three months after the Commission has circulated the dossier with the summary of the notification and the proposed conditions for placing on the market, other competent authorities may request the competent authority which proposes the endorsement to provide further information or change the conditions for placing on the market, giving their reasons for such requests.

3. If the competent authority which proposed the endorsement fails to comply with the requests of other authorities regarding further information, the risk assessement or the conditions of placing on the market, it shall give its reasons to the competent authority concerned.

4. Should it not be possible for the competent authorities concerned to reach an agreement, and should any competent authority feel, on the basis of scientific evidence, that the placing on the market of the product may pose risks to people or the environment, within this period of three months, the Commission shall take a decision in accordance with the procedure laid down in Article 20.

5. When the competent authority that received the original notification has provided satisfactory response to the requests of the other competent authorities, or if no suggestions have been made within the 60-day period, or when the Commission has taken a favourable decision in the case of Art. 11.4, it shall endorse the notification so that the product may be placed on the market.

6. Once a product has been endorsed, it may be used without further notification throughout the European Community insofar as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to.

7. Member States shall adopt all necessary measures to ensure that users comply with the conditions of use specified in the endorsement.

ARTICLE 12

Member States shall take all necessary measures to ensure that products containing or consisting of GMOs will be placed on the market after endorsement only if their labelling and packaging is that endorsed under Article 11.

ARTICLE 13

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

ARTICLE 14

1. Where a Member State has evidence that a product which has been properly notified and endorsed under this Directive constitues a serious risk to people or the environment, it may provisionally restrict or prohibit the use or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.

2. The Commission shall take a decision on the matter, within 3 months following the procedure laid down in Article 20.

ARTICLE 15

The Commission shall publish in the Official Journal a list of all the products receiving final endorsement under this Directive. For each product, the GMO(s) contained therein and the use(s) shall be clearly specified.

ARTICLE 16

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

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

PART D: FINAL PROVISIONS

ARTICLE 17

1. The notifier may indicate the information in the notifications submitted under this Articles 4 and 9 of this Directive, the disclosure of which might harm his competitive position, that should be kept secret. Verifiable justification must be given in such cases.

2. The competent authority shall decide on its own responsibility which information will be kept secret.

3. In no case may the following information be kept secret:

   - identity of the GMO(s), name and address of the notifier, purpose of the release or of the product, and site of release, or areas of use.

   - the evaluation of foreseeable effects, in particular any pathogenic and ecologically disruptive effects.

   - for experimental releases: methods and plans for monitoring the GMO(s), for decontaminating the area(s) of release, and for emergency response.

   - for placing on the market: methods for monitoring the GMO(s) contained in the product and for emergency response in case of misuse.

4. Confidential information brought to the attention either of the Commission or of a competent authority shall be kept secret.

ARTICLE 18

According to the procedure laid down in Article 20, the Commission shall adapt the annexes of this Directive to technical progress by:

- by amending new techniques to be covered or deleting as appropriate

- amending the notification requirements set out in Annexes II and III to take into account the potential hazard of the GMO(s).

ARTICLE 19

1. The Commission shall be assited by a Committee of an advisory nature composed of the representatives of the Member States and chaired by the representative of the Commission.

2. The Commission shall function in accordance with the procedures laid down in Article 20.

ARTICLE 20

1. Where the procedure laid down in this Article is followed, 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, if necessary by taking a vote. The opinion shall be recorded in the minutes; in addition, each Member State have the right to have its position recorded in the minutes. The Commission shall take the utmost account of the opinion delivered by the Committee. It shall inform the Committee of the manner in which its opinion has been taken into account.

ARTICLE 21

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

2. Every three years, Member States shall send the Commission a report on the measures taken to implement the provisions of this Directive, the first time being on 1st September 1991.

3. Every three years, the Commission shall publish a summary based on the reports referred to in paragraph 2, the first time being in 1992.

ARTICLE 22

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive within a period of 18 months from its notification.

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

ARTICLE 23

This Directive is addressed to the Member States.

ANNEX I

Genetically modified organisms are organisms which can be obtained by such techniques as recombinant DNA, micro-injection, macroinjection microencapsulation, nuclear and organel transplantation or genetic manipulation of viruses.

ANNEX II

The notifications for a deliberate release referred to in Article 4 and for placing on the market referred to in Article 9 must provide the information set out below.

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

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

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

1. IDENTIFICATION AND CHARACTERISTICS OF THE ORGANISM

a) Information relating to the parental organisms

- Scientific name
- Taxonomy
- Other names (usual name, strain name, cultivar name, etc.).
- Phenotypic and genetic markers.

b) Information relating to the recipient organism

- Description of identification and detection techniques

- Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques

- Description of the geographic distribution and of the natural habitat of the organism including information on natural predators, preys, parasites and competitors and symbionts

- Potential for genetic transfer and exchange with other organism

- Verification of the genetic stability of the organisms and factors affecting it

- Pathological, ecological and physiological traits of the organism:

  * Classification according to existing Community rules

  * Generation time in natural ecosystems, sexual and asexual reproductive cycle

  * Information on survival, including seasonality and the ability to form survival structures e.g.: seeds, spores or sclerotia

  * Pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms. Possible activation of latent viruses (proviruses). Ability to colonize other organisms

* Antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy

* Involvement in environmental processes: primary production, nutrient turn-over, decomposition of organic matter, respiration, etc..

c) Information relating to the genetic modification

- Methods used for the modification

- Methods used to construct and introduce the insert(s) into the recipient

- Purity of the insert from any unknown sequence

- Functional identity and location of the altered inserted nucleic acid segment(s) in question

- Description of any new genetic trait(s) or phenotypic characteristics which may be expressed or no longer expressed

- History of previous genetic manipulations with the parental organisms.

2. OTHER INFORMATION NECESSARY FOR RISK EVALUATION

a) Characteristics of the genetically modified organism (GMO) affecting survival, multiplication and dispersion

- Biological features which affect survival, multiplication and dispersion

- Behaviour in simulated natural environments, such as microcosms, growth rooms, greenhouses, etc.

- Known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, etc.)

- Sensitivity to specific agents

b) Interactions of the GMO with the biological systems:

- Predicted habitat of the GMO

- Genetic transfer capability

- Likelihood of post-release selection of genetic transfer leading to the expression of undesirable effects in the organisms released or/and in any other organism in the environment

- Measures employed to ensure genetic stability. Description of genetic traits which may prevent or minimise dispersal of genetic material

- Routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.

- Potential for excessive population increase in the environment

- Identification and description of the target organism

- Anticipated mechanism and result of interaction between the released GMO(s) and the target organism

- Identification and description of non-target organisms which may be affected unwittingly

- Known or predicted effects on non-target organisms in the environment impact on population levels of competitors, preys, hosts, symbionts, predators, parasites and pathogens

- Other potentially significant interactions with the environment.

3. GEOGRAPHICAL LOCATION OF THE SITE OF RELEASE (in the case of notifications for placing on the market, the site(s) of release will be the intended areas of use of the product)

a) Geographical location of the site(s), including:

- Physical or biological proximity to humans

- Size of local population

- Economic activities of local populations which are based on the natural resources of the area

b) Description of the site, including:

- Climatic characteristics

- Geographical, geological and pedological characteristics

- Flora and fauna, including crops, livestock and migratory species

- Surrounding ecosystems to which the organism could spread

c) A comparison of the natural habitat of the recipient organism with the proposed site(s) of release.

4. CONDITIONS OF THE DELIBERATE RELEASE (only for notifications under Article 4)

a) Description of the proposed deliberate release, including the program and the purpose(s) or objective(s)

b) Preparation of the site previous to the release

c) Size of the site

d) Method, amount, frequency and duration of the release

e) Methods of human intervention (mining, cultivation methods, etc..) on the site.

f) Worker safety measures during the release

g) Post-release treatment of the site

5. CONTROL AND EMERGENCY RESPONSE PLANS

a) Monitoring techniques

- Methods for tracing the GMO(s), and for monitoring its effects

- Detection and identification techniques to distinguish the GMO(s) from the parental organisms

- Specificity (to identify the GMO(s), and to distinguish them from the parental ones), sensitivity and reliability of the monitoring techniques

- Techniques for detecting transfer of the donated genetic material to other organisms

- For experimental releases, duration and frequency of the monitoring

b) Response plans in case of an unexpected spread of the organism

- Methods and procedures for controlling the GMO(s) in case of unexpected spread

- Methods for decontamination of the areas affected, e.g. eradiction of the GMO(s)

- Methods for disposal or sanitation of plants, animals, soils, etc.. that were exposed during or after the spread

- Methods for the isolation of the area affected by the spread

- Plans for protecting human and environmental health in case of the occurrence of an undesirable effect

c) Control of the release (only in case of notifications under Article 4)

- Methods and procedures to minimize the spread of the GMO(s) beyond the site of release

- Methods and procedures to protect the site from intrusion by unauthorized individuals.

ANNEX III

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

1. Name of the product and name(s) of GMO(s) contained there in

2. Name of the man 2. Name of the manufacturer or di address in the Community

3. Specificity of the product, exact conditions of use including, when appropriate, the type of environment and/or the geographical area(s) of the Community for which the product is suited

4. Type of expected use: industry, agriculture and skilled trades, consumer use by public at large.

B. The following information shall be provided, when relevant, in addition to that of Annex III.A, in accordance with Article 9.

1. Measures to take in case of unintended release or misuse.

2. Specific instructions or recommendations for storage and handling

3. Estimated production and/or imports to the Community

4. Proposed packaging. This must be appropriate so as to avoid unintended release of the GMO(s) during storage, or at a later stage

5. Proposed labelling. This must include, at least in summarized form, the information referred to in points A.1, A.2, A.3, B.1 and B.2 of this Annex.

DRAFT COUNCIL DIRECTIVE ON THE DELIBERATE RELEASE TO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS.

COMPETITIVENESS AND EMPLOYMENT IMPACT ASSESSMENT

I. WHAT IS THE MAIN REASON FOR INTRODUCING THE MEASURE

To approximate the Member States' laws and administrative provisions regarding the deliberate release to the environment of genetically modified organisms (GMOs) to the environment, and to ensure that these releases, for experimental and commercial purposes, will take place under conditions of human and environmental safety which are as high as reasonably practicable. These releases will involve, for example, microorganisms to be used as pesticides, toxic chemical degraders, etc, as well as plants or animals adapted to adverse environmental conditions, or resistant to diseases. As some Member States are introducing regulations on this matter, the elaboration of a Community directive is essential to avoid fragmentation of the market.

II. FEATURES OF THE BUSINESSES IN QUESTION

This a high-technology field, in which most activities are developped by large chemical manufacturers, and by research institutions very often supported by these large industries. The number of PMEs is small at this moment, and they are located in well-developped areas, not eligible for regional aid or the ERDF. However, the number of PMEs is potentially high in the future, as this currently expensive technology becomes more affordable. Many of the applications envisaged are products taylored for very specific uses: the sort of products appropriate for SMEs.

III. WHAT DIRECT OBLIGATIONS DOES THIS MEASURE IMPOSE ON BUSINESS?

The directive requires the researcher and/or the manufacturer to take measures to ensure human and environmental safety, and to submit a notification to a national competent authority. The notification will be submitted in all cases of releases of GMOs, as the little knowledge and experience on possible risks do not allow, at this moment, the exemption of certain categories of organisms. This notification, however extensive, should not require burdensome additional work: it should essentially consist of the information already available for the business in order to ensure the safety of the release. These notificatons will not be required of the final users of the product, i.e. farmers, environmental clean-up companies, etc.

IV. WHAT INDIRECT OBLIGATIONS ARE LOCAL AUTHORITIES LIKELY TO IMPOSE ON BUSINESSES?

To keep a high level of public information.

V. ARE THERE ANY SPECIAL MEASURES IN RESPECT OF SMEs?

No.

VI. WHAT IS THE LIKELY EFFECT ON:
(a) the competitiveness of businesses,
(b) employment?

(a) The harmonization of procedures at Community level should have a positive effect on the competitiveness of SMEs. On the other hand, the necessary adoption of safety measures (i.e.,fencing of the areas of release, further testing and the like) in order to make the releases as safe as possible may, in some occasions, be rather expensive. These costs could be, proportionally, more burdensome for SMEs.

(b) None.

VII. HAVE BOTH SIDES OF INDUSTRY BEEN CONSULTED?

This proposal has been discussed with the European Biotechnology Coordination group, composed of representatives from different European Industry's organisations: AMFEP, CEFIC, CIAA, EFPIA, GIFAP. The employee's side, however, has not been consulted.
Industry's view is that Community-wide harmonization of procedures is badly needed, but it expressed its reservation to an endorsement by regulatory bodies prior to the releases.