COMMISSION OF THE EUROPEAN COMMUNITIES

COM(91) 282 final

Brussels, 23 July 1991

Proposal for a

COUNCIL DECISION

CONCERNING THE SUMMARY NOTIFICATION INFORMATION FORMAT REFERRED TO IN ARTICLE 9 OF DIRECTIVE 90/220/EEC

(presented by the Commission)

EXPLANATORY MEMORANDUM

In accordance with the procedure laid down in Article 9 of Council Directive 90/220/EEC[1], the competent authorities must send to the Commission, within 30 days of its receipt, a summary of each notification received. The format of this summary must be established by the Commission in accordance with the procedure laid down in Article 21.

The Commission submitted for its opinion the proposed Decision to the Committee for the Release of Genetically Modified Organisms to the Environment.

Because the delegations were divided on the issue, the vote of the Committee did not reach the required qualified majority and it therefore did not give a favourable opinion on the proposal on 5 July 1991.

Pursuant to Article 21 of Directive 90/220/EEC, the Commission must submit without delay the proposal to the Council.

The Council must act by qualified majority within three months of receiving the proposal.

---

(1) OJ N° L117, 8.5.1990

Proposal for a Council Decision of ..... 1991 concerning the Summary Notification Information Format referred to in Article 9 of Directive 90/220/EEC.

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms(1), and in particular articles 9 and 21 thereof,

Having regard to the proposal from the Commission

Whereas the Competent Authorities appointed by the Member States have to send to the Commission a summary of each notification received under part B of Directive 90/220/EEC,

Whereas the Comission is required to establish, before 23 October 1991 the format of this summary,

Whereas the Committee for the Release of Genetically Modified Organisms to the Environment did not give a favourable opinion on the draft of the measure which was submitted to it by the Commission,

HAS ADOPTED THE FOLLOWING DECISION:

Article 1

The Competent Authorities appointed by Member States under Directive 90/220/EEC must use the annexed Summary Notification Information Format when sending to the Commission the summary of a notification received, as specified under part B of Directive 90/220/EEC.

Article 2

This Decision is addressed to the Member States

Done in Brussels, ...

(1) OJ N° L117, 8.5.1990

ANNEX

SUMMARY NOTIFICATION INFORMATION FORMAT

FOR GMO RELEASES FOR RESEARCH

AND DEVELOPMENT PURPOSES

In accordance with Directive 90/220/EEC
(Article 9)

INTRODUCTION

The Summary Notification Information Format has been established for the purposes and according to the procedures envisaged by Directive 90/220/EEC, article 9.

It is recognised that the Summary Notification Information Format is not designed to contain all the information required for carrying out an environmental risk assessment in the detail necessary for such an assessment. The information entered should, however, adequately reflect (in a condensed form) the information submitted to the Competent Authority according to Articles 5 and 6 of Directive 90/220/EEC under the conditions specified in the preface to Annex II. The space provided after each question is not indicative of the depth of the information required for the purposes of the Summary Notification Information Format.

GENERAL INFORMATION

1. Details of Notification

Member State of notification: .....

Notification number : .....

Date of acknowledgment of notification : .....

Title of the project : .....

.....

Proposed period of release : .....

2. Notifier

Name of institution or company: .....

.....

3. GMO characterisation

a) Indicate whether the GMO is a:

viroid ¦__¦

RNA virus ¦__¦

DNA virus ¦__¦

bacterium ¦__¦

fungus ¦__¦

plant ¦__¦

animal ¦__¦

other, please specify ¦__¦

.....

.....

b) Identity of the GMO:

.....

.....

4. **Is the same GMO release planned elsewhere in the Community (in conformity with article 5.1.) ?**

YES ¦__¦ NO ¦__¦ NOT KNOWN ¦__¦

If Yes, insert the country code(s) ¦__¦ ¦__¦ ¦__¦ .....

5. **Has the same GMO been notified for release elsewhere in the Community by the same notifier?**

YES ¦__¦ NO ¦__¦

If Yes:

- Member State of notification: .....
- Notification number : .....

INFORMATION RELATING TO ANNEX II
(DIRECTIVE 90/220/EEC)

A. INFORMATION RELATING TO THE RECIPIENT OR PARENTAL ORGANISMS FROM WHICH THE GMO IS DERIVED

1. Indicate whether the recipient or parental organism is a:

viroid ¦__¦

RNA virus ¦__¦

DNA virus ¦__¦

bacterium ¦__¦

fungus ¦__¦

plant ¦__¦

animal ¦__¦

other, please specify ¦__¦

.....

.....

---

2. a) Complete name:

i) order and/or higher taxon (for animals)
ii) family name (for plants)
iii) genus
iv) species
v) subspecies
vi) strain
vii) cultivar
viii) pathovar (biotype, ecotype, race, etc.)
ix) common name

---

3. **Geographical distribution of the organism:**

a) indigenous to the country where the notification is made:

Yes ¦__¦ No ¦__¦ Not known ¦__¦

b) indigenous to other EC countries:

i) Yes ¦__¦

If yes, indicate the type of ecosystem in which it is found:

Atlantic ¦__¦ Mediterranean ¦__¦ Continental ¦__¦

ii) No ¦__¦ Not known ¦__¦

c) is it regularly grown in the country where the notification is made?

Yes ¦__¦ No ¦__¦

d) is it regularly used in the country where the notification is made?

Yes ¦__¦ No ¦__¦

e) is it regularly kept in the country where the notification is made?

Yes ¦__¦ No ¦__¦

---

4. Natural habitat of the organism:

M a) if the organism is a microorganism

water ¦__¦

soil, free-living ¦__¦

soil in association with plant-root systems ¦__¦

in association with plant leaf/stem systems ¦__¦

in association with animals ¦__¦

other (specify) ¦__¦

P.A b) if the organism is an animal or a plant:

natural habitat or usual agroecosystem:

.....

.....

.....

---

5. a) Detection techniques:

.....

.....

b) Identification techniques:

.....

.....

---

6. Is the recipient organism classified under existing Community rules relating to the protection of human health and/or the environment?

YES ¦__¦ NO ¦__¦

if yes, specify: .....

.....

---

7. Is the recipient organism pathogenic or harmful in any other way (including its extracellular products), either living or dead?

YES ¦__¦ NO ¦__¦

If Yes,

a) to which of the following organisms?

humans ¦__¦

animals ¦__¦

plants ¦__¦

b) Give the relevant information specified under Annex II, II'A 11d/

.....

.....

---

8. Information concerning reproduction:

a) Generation time in natural ecosystems :

.....

b) Generation time in the ecosystem where the release will take place:

.....

c) Way of reproduction:

Sexual ¦__¦ Asexual ¦__¦ Vegetative ¦__¦

P d) In the case of plants:

i) Mode of reproduction:

autogamous ¦__¦

allogamous ¦__¦

ii) in case of allogamy

wind pollination |__|

insect pollination |__|

other |__|

e) Factors affecting reproduction

.....

.....

---

9. Survivability

a) Ability to form structures enhancing survival or dormancy:

i) seeds |__|

ii) tubers |__|

iii) bulbs |__|

iv) rhizomes |__|

v) endospores |__|

vi) cysts |__|

vii) sclerotia |__|

viii) asexual spores(fungi) |__|

ix) sexual spores (fungi) |__|

x) eggs |__|

xi) pupae |__|

xii) larvae |__|

x) other, please specify |__|

.....

b) Relevant factors affecting survivability:

.....

.....

---

10. a) Ways of dissemination:

.....

.....

b) Factors affecting dissemination:

.....

.....

---

11. Previous genetic modifications of the recipient or parental organism already notified for release in the country where the notification is made (give notification numbers):

.....

.....

.....

B. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Type of the genetic modification:

i) Insertion of genetic material ¦__¦

ii) Deletion of genetic material ¦__¦

iii) Base substitution ¦__¦

iv) Cell fusion ¦__¦

v) Other, please specify ¦__¦

---

2. Intended result of the genetic modification:

.....
.....
.....

---

3. a) Has a vector been used in the process of modification?

Yes ¦__¦ No ¦__¦

If No, go straight to question 5.

b) If Yes, is the vector wholly or partially present in the modified organism?

Yes ¦__¦ No ¦__¦

If No, go straight to question 5.

---

4. If the answer to 3b is Yes, supply the following information:

a) Type of vector:

plasmid ¦__¦

bacteriophage ¦__¦

virus ¦__¦

cosmid ¦__¦

phasmid ¦__¦

transposable element ¦__¦

other, please specify ¦__¦

.....
.....

b) Identity of the vector:

.....

.....

c) Host range of the vector:

.....

.....

d) Presence in the vector of sequences giving a selectable or identifiable phenotype:

	Yes	No
Antibiotic resistance	☐	☐
Heavy metal resistance	☐	☐
Other, specify	☐	☐

.....

e) Constituent fragments of the vector:

.....

.....

f) Method for introducing the vector into the recipient organism:

i) transformation ☐

ii) electroporation ☐

iii) macroinjection ☐

iv) microinjection ☐

v) infection ☐

vi) other, please specify ☐

.....

5. If the answer to question B.3.a) and b) is No, what was the method used to introduce the insert into the recipient/parental cell?

i) transformation ¦__¦

ii) microinjection ¦__¦

iii) microencapsulation ¦__¦

iv) macroinjection ¦__¦

v) other, please specify ¦__¦

.....

---

6. Information on the insert:

a) Composition of the insert:

.....

.....

b) Source of each constituent part of the insert :

.....

.....

c) Intended function of each constituent part of the insert in the GMO:

.....

.....

d) Location of the insert in the host organism:

- on a free plasmid ¦__¦

- integrated in the chromosome ¦__¦

- other, please specify ¦__¦

.....

e) Does the insert contain parts whose product or function are not known?

Yes ¦__¦ No ¦__¦

If Yes, please specify: .....
.....
.....

C. INFORMATION ON THE ORGANISM(S) FROM WHICH THE INSERT IS DERIVED (DONOR)

1. Indicate whether it is a:

viroid ¦__¦

RNA virus ¦__¦

DNA virus ¦__¦

bacterium ¦__¦

fungus ¦__¦

plant ¦__¦

animal ¦__¦

other, please specify ¦__¦

.....

.....

---

2. a) Complete name:

i) order and/or higher taxon (for animals)
ii) family name (for plants)
iii) genus
iv) species
v) subspecies
vi) strain
vii) cultivar
viii) pathovar
ix) common name

---

3. Is the organism pathogenic or harmful in any other way (including its extracellular products), either living or dead?

YES ¦__¦ NO ¦__¦ NOT KNOWN ¦__¦

if yes, specify the following:

a) to which of the following organisms?

humans ¦__¦

animals ¦__¦

plants ¦__¦

b) are the donated sequences involved in any way to the pathogenic or harmful properties of the organism?

YES ¦__¦ NO ¦__¦ NOT KNOWN ¦__¦

If yes, give the relevant information under Annex II, IIA, 11d:

.....

.....

---

4. Is the donor organism classified under existing Community rules relating to the protection of human health and the environment?

YES ¦__¦ NO ¦__¦

If yes, please specify:

.....

.....

.....

---

5. Do the donor and recipient organism exchange genetic material naturally?

YES ¦__¦ NO ¦__¦ Not known ¦__¦

D. INFORMATION RELATING TO THE GENETICALLY MODIFIED ORGANISM

1. Genetic traits and phenotypic characteristics of the recipient or parental organism which have been changed as a result of the genetic modification:

   a) Is the GMO different from the recipient as far as survivability is concerned?

   YES ¦__¦ NO ¦__¦ Not known ¦__¦

   If Yes, please specify:

   .....

   .....

   b) Is the GMO in any way different from the recipient as far as mode and/or rate of reproduction is concerned?

   YES ¦__¦ NO ¦__¦ Not known ¦__¦

   If Yes, please specify:

   .....

   .....

   c) Is the GMO in any way different from the recipient as far as dissemination is concerned?

   YES ¦__¦ NO ¦__¦ Not known ¦__¦

   If Yes, please specify:

   .....

   .....

---

2. Genetic stability of the genetically modified organism:

   .....

   .....

---

3. Is the GMO pathogenic or harmful in any other way (including its extracellular products), either living or dead?

   YES ¦__¦ NO ¦__¦ Not known ¦__¦

   If Yes,

a) to which of the following organisms?

humans ☐

animals ☐

plants ☐

b) Give the relevant information specified under Annex II, IIA 11d and IIC 2(i)

.....

.....

.....

.....

---

4. **Description of identification and detection methods:**

a) techniques used to detect the GMO in the environment:

.....

.....

b) techniques used to identify the GMO:

.....

.....

E. INFORMATION RELATING TO THE RELEASE

1. **Purpose of the release:**

.....

.....

.....

---

2. **Is the site of the release different from the natural habitat or from the ecosystem in which the recipient organism is regularly used, grown, kept or found?**

YES ¦__¦ NO ¦__¦

If Yes, please specify: .....

---

3. **Information concerning the release and the surrounding area:**

a) Geographical location (administrative region and where appropriate grid reference):

.....

b) Size of the site (m^2):

i) actual release site (m^2):

.....

ii) wider release area (m^2):

.....

c) Proximity to internationally recognised biotopes or protected areas (including drinking water reservoirs), which could be affected:

.....

.....

d) Flora and fauna including crops, livestock and migratory species which may potentially interact with the GMO:

.....

.....

.....

---

4. **Method and amount of Release:**

a) Quantities of GMOs to be released:

.....

.....

b) Duration of the operation:

.....

.....

c) Methods and procedures to avoid and/or minimize the spread of the GMOs beyond the site of the release:

.....

.....

.....

F. INTERACTIONS OF THE GMO WITH THE ENVIRONMENT AND POTENTIAL IMPACT ON THE ENVIRONMENT

1. Complete name of target organisms:

i) order and/or higher taxon (for animals)
ii) family name (for plants)
iii) genus
iv) species
v) subspecies
vi) strain
vii) cultivar
viii) pathovar
ix) common name

---

2. Anticipated mechanism and result of interaction between the released GMOs and the target organism:

.....

.....

.....

---

3. Other potentially significant interactions with other organisms in the environment:

.....

.....

.....

---

4. Is post-release selection <u>for</u> the GMO likely to occur?

YES ¦__¦ NO ¦__¦ Not known ¦__¦

If <u>Yes</u>, give details: .....

.....

---

5. Types of ecosystems to which the GMO could be disseminated from the site of release and in which it could become established:

.....

.....

.....

---

6. Complete name of non-target organisms which may be effected unwittingly:

   i) order and/or higher taxon (for animals)
   ii) family name (for plants)
   iii) genus
   iv) species
   v) subspecies
   vi) strain
   vii) cultivar
   viii) pathovar
   ix) common name

---

7. Likelihood of genetic exchange <u>in vivo</u>

   a) from the GMO to other organisms in the release ecosystem:

   .....

   .....

   b) from other organisms to the GMO:

   .....

   .....

---

8. Give references to relevant results from studies of the behaviour and characteristic of the GMO and its ecological impact carried out in simulated natural environments (e.g. microcosms, etc.):

   .....

   .....

   .....

   .....

   .....

G. INFORMATION RELATING TO MONITORING

1. Methods for monitoring the GMOs :

.....

.....

.....

---

2. Methods for monitoring ecosystem effects:

.....

.....

.....

---

3. Methods for detecting transfer of the donated genetic material from the GMO to other organisms:

.....

.....

.....

---

4. Spatial extent of the monitoring area (m^2):

.....

---

5. Duration of the monitoring:

.....

---

6. Frequency of the monitoring:

.....

H. INFORMATION ON POST-RELEASE AND WASTE TREATMENT

1. Post-release treatment of the site:

.....

.....

.....

---

2. Post-release treatment of the GMOs:

.....

.....

.....

3a) Type and amount of waste generated:

.....

.....

3b) Treatment of waste:

.....

.....

I. INFORMATION ON EMERGENCY RESPONSE PLANS

1. Methods and procedures for controlling GMOs in case of unexpected spread:

.....

.....

.....

---

2. Methods for decontamination of the areas affected:

.....

.....

.....

---

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

.....

.....

.....

---

4. Plans for protecting human health and the environment in case of the occurence of an undesirable effect:

.....

.....

.....

****

ISSN 0254-1475

COM(91) 282 final

DOCUMENTS

EN **01**

Catalogue number : CB-CO-91-326-EN-C

ISBN 92-77-74667-X

Office for Official Publications of the European Communities
L-2985 Luxembourg