II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 4 November 1991

concerning the Summary Notification Information Format referred to in Article 9 of Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms

(91/596/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 pursuant to part B of Directive 90/220/EEC;

Whereas the Commission is required to establish in good time the format of this summary, so as to enable the said Directive to be implemented before 23 October 1991;

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 THIS DECISION:

Article 1

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

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 4 November 1991.

For the Council
The President
H. VAN DEN BROEK

(1) OJ No L 117, 8. 5. 1990, p. 15.

ANNEX

SUMMARY NOTIFICATION INFORMATION FORMAT FOR RELEASES OF GENETICALLY MODIFIED ORGANISMS FOR RESEARCH AND DEVELOPMENT PURPOSES

(in accordance with Article 9 of Directive 90/220/EEC)

INTRODUCTION

The Summary Notification information Format has been established for the purposes and according to the procedures envisaged by Article 9 of Directive 90/220/EEC.

It is recognized 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 pursuant to the conditions specified in the preface to Annex II. The space provided after each question is not indicative of the degree of precision 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 body or company: .....

.....

3. *GMO characterization*

(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 accordance 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

of 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 ☐

.....

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2. *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

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3. *Geographical distribution of the organism*

(a) Indigenous to the country where the notification is made:

YES ☐ NO ☐ NOT KNOWN ☐

(b) Indigenous to other Community 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 micro-organism:

water ☐
soil, free-living ☐
soil in association with plant-root systems ☐
in association with plant-leaf/stem systems ☐
in association with animals ☐
other (specify) ☐

A, P (b) If the organism is an animal or a plant:

natural habitat or usual agro-ecosystem: .....
.....
.....
.....

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, Chapter II A, point 11 d:

.....
.....

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 ☐

both ☐

(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 ☐

(xiii) other, please specify ☐

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(b) Factors affecting survivability: .....

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10. (a) Ways of dissemination: .....

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(b) Factors affecting dissemination: .....

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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): .....

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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: .....

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.....

.....

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 3 (b) 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, please specify	☐	☐

.....

(e) constituent fragments of the vector: .....

.....

.....

(f) method for introducing the vector into the recipient organism:

(i) transformation ☐
(ii) electroporation ☐
(iii) macro-injection ☐
(iv) micro-injection ☐
(v) infection ☐
(vi) other, please specify ☐

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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) tranformation ☐
(ii) micro-injection ☐
(iii) micro-encapsulation ☐
(iv) macro-injection ☐
(v) other, please specify ☐

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6. *Information on the insert*

(a) Composition of the insert: .....

.....

.....

(b) Source of each constituent part of the insert: .....

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.....

(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 funtion 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. *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

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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 inserted sequences involved in any way in the pathogenic or harmful properties of the organism?

YES ☐ NO ☐ NOT KNOWN ☐

If yes, give the relevant information under Annex II, Chapter 11. A, point 11 (d): .....

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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: .....

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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 specifiy: .....

.....

.....

(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 release is concerned?

YES ☐ NO ☐ NOT KNOWN ☐

If yes, please specify: .....

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.....

2. Genetic stability of the genetically modified organism: .....

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.....

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, Chapter 11. A, point 11 (d) and Chapter 11. C, point 2 (i):

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4. *Description of identification and detection methods*

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

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(b) techniques used to identify the GMO: .....

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E. INFORMATION RELATING TO THE RELEASE

1. Purpose of the release: .....

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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: .....

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

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

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

(i) actual release site (m^2): .....

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(ii) wider release area (m^2): .....

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

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

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4. *Method and amount of release*

(a) quantities of GMOs to be released: .....

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(b) duration of the operation: .....

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

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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:

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

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4. Is post-release selection for the GMO likely to occur?

YES ☐ NO ☐ NOT KNOWN ☐

If yes, give details: .....

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

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6. *Complete name of non-target organisms which may be affected 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 in vivo*

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

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.....

(b) from other organisms to the GMO: .....

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

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G. INFORMATION RELATING TO MONITORING

1. Methods for monitoring the GMOs: .....

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2. Methods for monitoring ecosystem effects: .....

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

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

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5. Duration of the monitoring: .....

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6. Frequency of the monitoring: .....

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H. INFORMATION ON POST-RELEASE AND WASTE TREATMENT

1. Post-release treatment of the site: .....

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2. Post-release treatment of the GMOs: .....

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3. (a) Type and amount of waste generated: .....

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(b) Treatment of waste: .....

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I. INFORMATION ON EMERGENCY RESPONSE PLANS

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

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2. Methods for decontamination of the areas affected: .....

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

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

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