Proposal for a Council Decision establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market

(2002/C 262 E/22)

COM(2002) 361 final

(Submitted by the Commission on 4 July 2002)

EXPLANATORY MEMORANDUM

1. Under Part B of Directive 2001/18/EC, prior notification must be given to the competent national authority of the planned release of a genetically modified organism (GMO), or of a combination of such organisms, for purposes other than for placing on the market.

2. Within the framework established by Directive 2001/18/EC for the exchange of information between the competent authorities and the Commission, the authority must then send a summary, in accordance with a specific format, of the notification to the Commission, which in turn must forward copies to the other Member States.

3. That format should reflect the need to enable the fullest possible exchange of relevant information, presented in a standardised and easily comprehensible manner, without prejudice to the fact that the information thus provided cannot serve as the basis for an environmental risk assessment.

4. Article 11(1) of the Directive stipulates that the summary notification information format must be drawn up in accordance with the procedure laid down in Article 30. A draft of the measures to be taken has accordingly been submitted for opinion to the committee set up under Article 30 of the Directive.

5. The committee has not delivered an opinion on the proposal. In such a case, Article 30 stipulates that the Commission must forthwith propose to the Council the measures to be adopted and inform the European Parliament thereof. The Council must then act by qualified majority.

6. If, by the expiry of the time limit, the Council has not adopted the proposed implementing measures or has not indicated its opposition to the proposed implementing measures, they shall be adopted by the Commission.

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/18/EC of the European Parliament and of the Council [1] of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Directive 90/220/EEC, and in particular Article 11(1) thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) Under Part B of Directive 2001/18/EC, prior notification must be given to the competent national authority of the planned release of a genetically modified organism (GMO), or of a combination of such organisms, for purposes other than for placing on the market.

(2) Within the framework established by the Directive 2001/18/EC for the exchange of information between the competent authorities and the Commission, the authority must then send a summary, in accordance with a specific format, of the notification to the Commission, which in turn must forward copies to the other Member States.

(3) That format should reflect the need to enable the fullest possible exchange of relevant information, presented in a standardised and easily comprehensible manner, without prejudice to the fact that the information thus provided cannot serve as the basis for an environmental risk assessment.

(4) The committee set up under Article 30(2) of Directive 2001/18/EC was consulted on 12 June 2002 and has not delivered an opinion on the Commission's proposal for a Decision,

HAS ADOPTED THIS DECISION:

Article 1

For the purposes of summarising, for transmission to the Commission, notifications received pursuant to Article 6 of Directive 2001/18/EC, the competent authorities appointed by Member States under that Directive shall use the Summary Notification Information Format set out in the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

[1] OJ L 106, 17.4.2001, p. 1.

ANNEX

SUMMARY NOTIFICATION INFORMATION FORMAT FOR THE DELIBERATE RELEASE OF A GMO OR A COMBINATION OF GMOs FOR PURPOSES OTHER THAN FOR PLACING ON THE MARKET

INTRODUCTION

The Summary Notification Information Format for deliberate releases of a GMO or of a combination of GMOs, has been established for the purposes and according to the procedures envisaged by Article 11 of Directive 2001/18/EC.

It is recognised that this Format is not designed to accommodate all the information required for carrying out an environmental risk assessment.

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.

The Summary Notification Information Format consists of a Part 1 and a Part 2.

Part 1 applies to products consisting of or containing genetically modified higher plants. The term 'higher plants' means plants which belong to the taxonomic group Gymnospermae and Angiospermae. Part 1 contains the following sections:

A. General information

B. Information on the genetically modified plant

C. Information relating to the experimental release

D. Summary of the potential environmental impact of the release of the GMPts

E. Brief description of any measures taken for the management of risks

F. Summary of planned field trials designed to gain new data on the environmental and human health impact of the release.

In Part 1 the information entered should, however, adequately reflect (in a condensed form) the information submitted to the competent authority in accordance with Articles 6 and 7 of Directive 2001/18/EC under the conditions specified in the preface to Annex III B.

Part 2 applies to products consisting of or containing genetically modified organisms other than higher plants and contains the following sections:

A. General Information

B. Information relating to the recipient or parental organisms from which the GMO is derived

C. Information relating to the genetic modification

D. Information on the organism(s) from which the insert is derived (donor)

E. Information relating to the genetically modified organism

F. Information relating to the release

G. Interactions of the GMO with the environment and potential impact on the environment

H. Information relating to monitoring

I. Information on post-release and waste treatment

J. Information on emergency response plans.

In Part 2 the information entered should, however, adequately reflect (in a condensed form) the information submitted to the competent authority in accordance with Articles 6 and 7 of Directive 2001/18/EC under the conditions specified in the preface to Annex III A.

PART 1

SUMMARY NOTIFICATION INFORMATION FORMAT FOR THE RELEASE OF GENETICALLY MODIFIED HIGHER PLANTS (ANGIOSPERMAE AND GYMNOSPERMAE)

A. GENERAL INFORMATION

1. **Details of notification**

(a) Notification number
(b) Date of acknowledgement of notification
(c) Title of the project
(d) Proposed period of release

2. **Notifier**

Name of institute or company

3. **Is the same GMPt release planned elsewhere, inside or outside the Community (in conformity with Article 6(1)) by the same notifier?**

Yes ☐	No ☐
If yes, insert the country code(s):	

4. **Has the same GMPt been notified for release elsewhere, inside or outside the Community, by the same notifier?**

Yes ☐	No ☐
If yes, notification number:	

B. INFORMATION ON THE GENETICALLY MODIFIED PLANT

1. **Identity of the recipient or parental plant**

(a) Family name
(b) Genus
(c) Species
(d) Subspecies (if applicable)
(e) Cultivar/breeding line (if applicable)
(f) Common name

2. **Description of the traits and characteristics which have been introduced or modified, including marker genes and previous modifications**

3. **Type of the genetic modification**

(a) Insertion of genetic material
(b) Deletion of genetic material
(c) Base substitution
(d) Cell fusion
(e) Other, please specify

4. **In the case of insertion of genetic material, give the source and intended function of each constituent fragment of the region to be inserted**

5. **In the case of deletion or other modification of genetic material, give information on the function of the deleted or modified sequences**

6. **Brief description of the method used for the genetic modification**

7. **If the recipient or parental plant is a forest tree species, describe ways and extent of dissemination and specific factors affecting dissemination**

C. INFORMATION RELATING TO THE EXPERIMENTAL RELEASE

1. **Purpose of the release (including any relevant information available at this stage) such as agronomic purposes, test of hybridisation, changed survivability or dissemination, test of effects on target or non-target organisms**

2. **Geographical location of the release site**

3. **Size of the site (m^2)**

4. **Relevant data regarding previous releases carried out with the same GM-plant, if any, specifically related to the potential environmental and human health impacts from the release**

D. SUMMARY OF THE POTENTIAL ENVIRONMENTAL IMPACT OF THE RELEASE OF THE GMPTS IN ACCORDANCE WITH ANNEX II, D2 OF DIRECTIVE 2001/18/EC

Note especially if the introduced traits could directly or indirectly confer an increased selective advantage in natural environments; also explain any significant expected environmental benefits

E. BRIEF DESCRIPTION OF ANY MEASURES TAKEN FOR THE MANAGEMENT OF RISKS INCLUDING ISOLATION DESIGNED TO LIMIT DISPERSAL, FOR EXAMPLE MONITORING AND POST-HARVEST MONITORING PROPOSALS

F. SUMMARY OF PLANNED FIELD TRIALS DESIGNED TO GAIN NEW DATA ON THE ENVIRONMENTAL AND HUMAN HEALTH IMPACT OF THE RELEASE (WHERE APPROPRIATE)

PART 2

SUMMARY NOTIFICATION INFORMATION FORMAT FOR THE RELEASE OF GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS

in accordance with Article 11 of Directive 2001/18/EC

A. GENERAL INFORMATION

1. **Details of notification**

(a) Member State of notification
(b) Notification number
(c) Date of acknowledgement of notification
(d) Title of the project
(e) 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 ☐ animal ☐ — mammal ☐ — insect ☐ — fish ☐ — other animal ☐ (please specify phylum, class) other, please specify (kingdom, phylum and class)
(b) Identity of the GMO (genus and species)
(c) Genetic stability — according to Annex IIIa, II, A(10)

4. **Is the same GMO release planned elsewhere in the Community (in conformity with Article 6(1)), by the same notifier?**

Yes ☐	No ☐
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	

6. **Has the same GMO been notified for release or placing on the market outside the Community by the same or other notifier?**

Yes ☐	No ☐
If yes: — Member State of notification — Notification number	

7. **Summary of the potential environmental impact of the release of the GMOs**

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

1. **Recipient or parental organism characterisation:**

(a) Indicate whether the recipient or parental organism is a:

Viroid	☐	
RNA virus	☐	
DNA virus	☐	
bacterium	☐	
fungus	☐	
animal	☐	
— mammal	☐	
— insect	☐	
— fish	☐	
— other animal	☐	(please specify phylum, class)

other, please specify

2. **Name**

(i) Order and/or higher taxon (for animals)
(ii) Genus
(iii) Species
(iv) Subspecies
(v) Strain
(vi) pathovar (biotype, ecotype, race, etc.)
(vii) common name

3. **Geographical distribution of the organism**

(a) Indigenous to, or otherwise established in, the country where the notification is made:

Yes ☐ No ☐ Not known ☐

(b) Indigenous to, or otherwise established in, other EC countries:

(i) Yes ☐

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

Atlantic ☐

Mediterranean ☐

Arctic ☐

Alpine ☐

Continental ☐

(ii) No ☐

(iii) Not known ☐

(c) Is it frequently used in the country where the notification is made?

Yes ☐ No ☐

(d) Is it frequently kept in the country where the notification is made?

Yes ☐ No ☐

4. **Natural habitat of the organism**

(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 ☐

iin association with animals ☐

other (specify)

(b) If the organism is an animal: natural habitat or usual agroecosystem:

5. (a) **Detection techniques**

5. (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 significantly 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 ☐ other ☐		
(b) give the relevant information specified under Annex III A, point II (A), 11/(d) of Directive 2001/18/EC		

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 ☐
(d) Factors affecting reproduction:

9. **Survivability**

(a) Ability to form structures enhancing survival or dormancy:	
(i) endospores	☐
(ii) cysts	☐
(iii) sclerotia	☐
(iv) asexual spores (fungi)	☐
(v) sexual spores (fungi)	☐
(vi) eggs	☐
(vii) pupae	☐
(viii) larvae	☐
(ix) other, please specify	
(b) Relevant factors affecting survivability:	

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

10. (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)**

C. 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 outcome 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	

3. (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 ☐

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 ☐

Other, specify

Indication of which antibiotic resistance gene is inserted

(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 in the process of modification?**

(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

D. 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	☐	
animal	☐	
— mammal	☐	
— insect	☐	
— fish	☐	
— other animal	☐	(please specify phylum, class)
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/breeding line
(viii) pathovar
(ix) common name

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

Yes ☐	No ☐	Not known ☐
If yes, please specify the following (a) to which of the following organisms?: humans ☐ animals ☐ plants ☐ other ☐		
(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 III A, point II (A), 11(d):		

4. **Is the donor organism classified under existing Community rules relating to the protection of human health and the environment, such as Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work?**

Yes ☐	No ☐
If yes, please specify	

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

Yes ☐	No ☐	Not known ☐

E. 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 ☐

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 know ☐

Please specify

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

Yes ☐ No ☐ Not known ☐

Please specify

(d) Is the GMO in any way different from the recipient as far as pathogenicity is concerned?

Yes ☐ No ☐ Not known ☐

Please specify

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

3. **Is the GMO significantly pathogenic or harmful in any 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 ☐

other ☐

(b) give the relevant information specified under Annex III A, point II (A), 11(d) and II (C) 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

F. INFORMATION RELATING TO THE RELEASE

1. **Purpose of the release (including any significant potential environmental benefits that may be expected)**

2. **Is the site of the release different from the natural habitat or from the ecosystem in which the recipient or parental organism is regularly used, 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 minimise the spread of the GMOs beyond the site of the release

5. **Short description of average environmental conditions (weather, temperature etc.)**

6. **Relevant data regarding previous releases carried out with the same GMO, if any, specially related to the potential environmental and human health impacts from the release**

G. INTERACTIONS OF THE GMO WITH THE ENVIRONMENT AND POTENTIAL IMPACT ON THE ENVIRONMENT, IF SIGNIFICANTLY DIFFERENT FROM THE RECIPIENT OR PARENT ORGANISM

1. **Name of target organisms (if applicable)**

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

2. **Anticipated mechanism and result of interaction between the released GMOs and the target organism (if applicable)**

3. **Any other potentially significant interactions with other organisms in the environment**

4. **Is post-release selection such as increased competitiveness, increased invasiveness for the GMO likely to occur?**

Yes ☐	No ☐	Not known ☐
Please 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 (taking into account the nature of the receiving environment) may be unintentionally significantly harmed by the release of the GMO**

(i) order and/or higher taxon (for animals)
(ii) family name (for plants)
(iii) genus

(iv) species
(v) subspecies
(vi) strain
(vii) cultivar/breeding line
(viii) pathovar
(ix) common name

7. **Likelihood of genetic exchange in vivo**

(a) from the GMO to other organisms in the release ecosystem:
(b) from other organisms to the GMO:
(c) likely consequences of gene transfer:

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

9. **Possible environmentally significant interactions with biogeochemical processes (if different from the recipient or parental organism)**

H. 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. **Size of the monitoring area (m^2)**

5. **Duration of the monitoring**

6. **Frequency of the monitoring**

I. INFORMATION ON POST-RELEASE AND WASTE TREATMENT

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

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

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

3. (b) **Treatment of waste**

J. INFORMATION ON EMERGENCY RESPONSE PLANS

1. **Methods and procedures for controlling the dissemination of the GMO(s) in case of unexpected spread**

2. **Methods for removal of the GMO(s) of the areas potentially affected**

3. **Methods for disposal or sanitation of plants, animals, soils etc. that could be exposed during or after the spread**

4. **Plans for protecting human health and the environment in the event of an undesirable effect**