Proposal for a Council Decision establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products

(2002/C 262 E/23)

COM(2002) 362 final

(Submitted by the Commission on 4 July 2002)

EXPLANATORY MEMORANDUM

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

2. That notification comprises, *inter alia*, a summary of the relevant dossier, which the competent authority must send to the competent authorities of the other Member States and to the Commission, and which the Commission must immediately make available to the public. That summary must be drawn up in accordance with a particular format.

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 13(2)(h) 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 13(2)(h) thereof,

Having regard to the proposal from the Commission,

Whereas:

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

(2) That notification comprises, *inter alia*, a summary of the relevant dossier, which the competent authority must send to the competent authorities of the other Member States and to the Commission, and which the Commission must immediately make available to the public. That summary must be drawn up in accordance with a particular format.

(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 drawing up the summary of the dossier for submission to the competent national authority pursuant to Article 13(2)(h) of Directive 2001/18/EC, the notifier shall use the Summary 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 INFORMATION FORMAT IN RELATION TO THE PLACING ON THE MARKET OF A GMO OR A COMBINATION OF GMOs AS OR IN PRODUCTS

INTRODUCTION

The following format must be used for the summary of the dossier to accompany a notification, for submission to the competent national authority, concerning the placing on the market of a GMO or a combination of GMOs as or in products.

This document, when completed, will present a summary of the information entered under the corresponding points of the full dossier. It is recognised, therefore, that the risk assessment required under Directive 2001/18/EC cannot be carried out solely on the basis of this document.

The space provided after each question is not indicative of the depth of the information required for the purposes of the Summary Information Format.

The Summary Information Formatis divided into Parts 1 and 2.

Part 1 applies to products consisting of or containing genetically modified organisms other than higher plants and contains the following sections:

A. General information

B. Nature of the GMOs contained in the product

C. Predicted behaviour of the product

D. Information relating to previous releases

E. Information relating to the monitoring plan.

Part 2 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 2 contains the following sections:

A. General information

B. Nature of the GMHP contained in the product

C. Information relating to previous releases

D. Information relating to the monitoring plan.

PART 1

SUMMARY INFORMATION FORMAT FOR PRODUCTS CONTAINING GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS

A. GENERAL INFORMATION

1. **Details of notification**

(a) Member State of notification
(b) Notification number
(c) Name of the product (commercial and other names)
(d) Date of acknowledgement of notification

2. **Notifier/Producer/Importer**

(a) Name of notifier	
(b) Address of notifier	
(c) The notifier is:	domestic producer ☐ importer ☐
(d) In the case of an import	
(i) Name of producer	
(ii) Address of producer	

3. **Characterisation of the GMOs contained in the product**

Indicate the name and nature of each type of GMO contained in the product

4. **General description of the product**

(a) Type of product
(b) Composition of the product
(c) Specificity of the product
(d) Types of users
(e) Any special conditions of use and handling suggested as a condition of the authorisation applied for
(f) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for
(g) Any type of environment to which the product is unsuited
(h) Estimated potential annual demand (i) in the Community (ii) in export markets for EC supplies
(i) Unique identification code(s) of the GMO(s)

5. **Has the combination of GMOs contained in the product been notified under Part B of Directive 2001/18/EC by the same notifier?**

Yes ☐	No ☐
(i) If yes, give country and notification number	
(ii) If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC.	

6. **Is the product being simultaneously notified to another Member State by the same notifier?**

Yes ☐	No ☐
If yes, please specify:	

7. **Has another product with the same combination of GMOs been placed on the EC market by another notifier?**

Yes ☐	No ☐	Not known ☐
If yes, please specify		

8. **Information on releases of the same GMOs or of the same combination of GMOs previously or currently notified and/or carried out by the notifier either inside or outside the Community**

9. **Specify instructions and or recommendations for storage and handling, including any mandatory restrictions proposed as a condition of the authorisation applied for**

10. **Proposed packaging**

11. **Any proposed labelling requirements, in addition to those required by law**

12. **Measures to take in the event of unintended release or misuse**

13. **Measures for waste disposal and treatment (if applicable)**

B. NATURE OF THE GMOS CONTAINED IN THE PRODUCT

INFORMATION RELATING TO THE RECIPIENT OR PARENTAL ORGANISM(S) FROM WHICH THE GMO IS DERIVED

14. **Scientific name and common names**

15. **Phenotypic and genetic traits**

16. **Geographical distribution and natural habitat of the organism**

17. **Genetic stability of the organism and factors affecting it**

18. **Potential for genetic transfer and exchange with other organisms and the likely consequences of gene transfer**

19. **Information concerning reproduction and factors affecting it**

20. **Information on survival and factors affecting it**

21. **Ways of dissemination and factors affecting it**

22. **Interactions with the environment**

23. (a) **Detection techniques**

23. (b) **Identification techniques**

24. **Classification under existing Community rules concerning the protection of human health and/or environment**

25. (a) **Pathogenic characteristics**

25. (b) **Other harmful characteristics of the organisms living or dead, including its extracellular products**

26. **Nature and description of known extrachromosomal genetic elements**

27. **Summary of known history of previous genetic modifications**

INFORMATION RELATING TO THE GENETIC MODIFICATION

28. **Methods used for the genetic modification**

29. **Characteristics of the vector**

(a) Nature and source of the vector
(b) Description of the vector construction
(c) Genetic map and/or restriction map of the vector
(d) Sequence data
(e) Information on the degree to which the vector contains sequences whose product or function area is not known
(f) Genetic transfer capabilities of the vector
(g) Frequency of mobilisation of the vector
(h) Part of the vector which remains in the GMO

30. **Information on the insert**

(a) Methods used to construct the insert
(b) Restriction sites
(c) Sequence of the insert
(d) Origin and function of each constituent part of the insert in the GMO
(e) Information on the degree to which the insert is limited to the required function
(f) Location of the insert in the GMO

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

31. **Scientific and other names**

32. (a) **Pathogenic characteristics of the donor organism**

32. (b) **Other harmful characteristics of the organism living or dead, including its extracellular products**

33. **If the donor organism has any pathogenic or harmful characteristics, indicate whether the donated sequences are in any way involved in them**

34. **Classification under existing Community rules relating to the protection of human health and the environment**

35. **Potential for natural exchange of genetic material between the donor(s) and recipient organism**

INFORMATION RELATING TO THE GMO(S) CONTAINED IN THE PRODUCT

36. **Description of genetic traits or phenotypic characteristics, if different from that of the recipient or parental organism(s)**

37. **Genetic stability of the GMO, if different from that of the recipient or parental organism(s)**

38. **Rate and level of expression of the new genetic material**

39. **Activity of the expressed proteins**

40. (a) **Description of detection techniques for the GMO in the environment, if different from that of the recipient or parental organism(s)**

40. (b) **Description of identification techniques to distinguish the GMO from the recipient or parental organism**

41. **Health considerations**

(a) Toxic or allergenic effects of the non-viable GMOs and/or their metabolic products, if significantly different from those of the recipient/parental organism
(b) Product hazards, if significant
(c) Comparison of the GMO with the donor, recipient or parental organism regarding pathogenicity, if significantly different
(d) Capacity for colonisation, if significantly different from the recipient or parental organism(s)
(e) If the organism is more pathogenic than the recipient or parental organism(s) to humans who are immuno competent, supply the information specified in Annex III A, Part II C 2(l) (iv)

INTERACTIONS OF THE GMO WITH THE ENVIRONMENT

42. **Survival, multiplication and dissemination of the GMO(s) in the environment if different from the recipient or parental organism**

43. **Environmental impacts of the GMOS(s) if different from the recipient or parental organism**

C. PREDICTED BEHAVIOUR OF THE PRODUCT, IF DIFFERENT FROM THE RECIPIENT OR PARENT ORGANISM(S)

ENVIRONMENTAL IMPACT OF THE PRODUCT

HUMAN HEALTH EFFECTS OF THE PRODUCT, IF DIFFERENT FROM THE RECIPIENT OR PARENT ORGANISM(S)

D. INFORMATION RELATING TO PREVIOUS RELEASES

HISTORY OF PREVIOUS RELEASES NOTIFIED UNDER PART B OF THE DIRECTIVE (IF APPLICABLE)

1. **Notification number**

2. **Release site**

3. **Aim of the release**

4. **Duration of the release**

5. **Duration of post-release monitoring**

6. **Aim of post-release monitoring**

7. **Conclusions of post-release monitoring**

8. **Results of the release with respect to any risk to human heath and the environment according to Article 8 of Directive 90/220/EEC or Article 10 of Directive 2001/18/EC**

HISTORY OF PREVIOUS RELEASES CARRIED OUT INSIDE OR OUTSIDE THE COMMUNITY

1. **Release country**

2. **Authority overseeing the release**

3. **Release site**

4. **Aim of the release**

5. **Duration of post-release monitoring**

6. **Aim of post-release monitoring**

7. **Conclusions of post-release monitoring**

8. **Results of the release with respect to any risk to human health and the environment**

HISTORY OF PREVIOUS WORK RELEVANT TO RISK ASSESSMENT PRIOR TO COMMERCIALISATION

E. INFORMATION RELATING TO THE MONITORING PLAN — IDENTIFIED TRAITS, CHARACTERISTICS AND UNCERTAINTIES RELATED TO THE GMO OR ITS INTERACTION WITH THE ENVIRONMENT THAT SHOULD BE ADDRESSED IN THE POST-COMMERCIALISATION MONITORING PLAN

PART 2

SUMMARY INFORMATION FORMAT FOR PRODUCTS CONTAINING GENETICALLY MODIFIED HIGHER PLANTS (GMHPs)

A. GENERAL INFORMATION

1. **Details of notification**

(a) Member State of notification
(b) Notification number
(c) Name of the product (commercial and other names)
(d) Date of acknowledgement of notification

2. **Notifier**

(a) Name of notifier
(b) Address of notifier
(c) Is the notifier: domestic manufacturer ☐ importer ☐
(d) In the case of an import the name and address of the manufacturer shall be given

3. **General description of the product**

(a) Name of the recipient or parental plant and the intended function of the genetic modification
(b) Any specific form in which the product must not be placed on the market (seeds, cut-flowers, vegetative parts, etc.) as a proposed condition of the authorisation applied for
(c) Intended use of the product and types of users
(d) Any specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for
(e) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for
(f) Any type of environment to which the product is unsuited
(g) Any proposed packaging requirements
(h) Any proposed labelling requirements in addition to those required by law
(i) Estimated potential demand (i) in the Community (ii) in export markets for EC supplies
(j) Unique identification code(s) of the GMO(s)

4. **Has the GMHP referred to in this product been notified under Part B of Directive 2001/18/EC and/or Directive 90/220/EEC?**

Yes ☐	No ☐
(i) If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC	

5. **Is the product being simultaneously notified to another Member State?**

Yes ☐	No ☐
(i) If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC	

OR

Has the product been notified in a third country either previously or simultaneously?

Yes ☐	No ☐
If yes, please specify	

6. **Has the same GMHP been previously notified for marketing in the Community?**

Yes ☐	No ☐
If yes, give notification number and Member State	

7. **Measures to take in case of unintended release or misuse as well as measures for disposal and treatment**

B. NATURE OF THE GMHP CONTAINED IN THE PRODUCT

INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

8. **Complete name**

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

9. (a) **Information concerning reproduction**

(i) Mode(s) of reproduction

(ii) Specific factors affecting reproduction, if any
(iii) Generation time

9. (b) **Sexual compatibility with other cultivated or wild plant species**

10. **Survivability**

(a) Ability to form structures for survival or dormancy
(b) Specific factors affecting survivability, if any

11. **Dissemination**

(a) Ways and extent of dissemination
(b) Specific factors affecting dissemination, if any

12. **Geographical distribution of the plant**

13. **In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts**

14. **Potentially significant interactions of the plant with other organisms in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms**

15. **Phenotypic and genetic traits**

INFORMATION RELATING TO THE GENETIC MODIFICATION

16. **Description of the methods used for the genetic modification**

17. **Nature and source of the vector used**

18. **Size, source (name of donor organism(s)) and intended function of each constituent fragment of the region intended for insertion**

INFORMATION RELATING TO THE GMHP

19. **Description of the trait(s) and characteristics which have been introduced or modified**

20. **Information on the sequences actually inserted/deleted/modified**

(a) Size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP
(b) In case of deletion, size and function of the deleted region(s)
(c) Location of the insert in the plant cells (integrated in the chromosome, chloroplast, mitochondrion, or maintained in a non-integrated form), and methods for its determination
(d) Copy number and genetic stability of the insert
(e) In case of modifications other than insertion or deletion, describe function of the modified genetic material before and after the modification as well as direct changes in expression of genes as a result of the modification

21. **Information on the expression of the insert**

(a) Information on the expression of the insert and methods used for its characterisation
(b) Parts of the plant where the insert is expressed (e.g. roots, stem, pollen, etc.)

22. **Information on how the GMHP differs from the recipient plant in**

(a) Mode(s) and/or rate of reproduction
(b) Dissemination
(c) Survivability
(d) Other differences

23. **Potential for transfer of genetic material from the GMHP to other organisms**

24. **Information on any harmful effects on human health and the environment, arising from the genetic modification**

25. **Information on the safety of the GMHP to animal health, where the GMHP is intended to be used in animal feedstuffs, if different from that of the recipient/parental organism(s)**

26. **Mechanism of interaction between the GMHP and target organisms (if applicable), if different from that of the recipient/parental organism(s)**

27. **Potentially significant interactions with non-target organisms, if different from the recipient or parental organism(s)**

28. **Description of detection and identification techniques for the GMHP, to distinguish it from the recipient or parental organism(s)**

INFORMATION ON THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE OF THE GMHP

29. **Potential environmental impact from the release or the placing on the market of GMOs (Annex II, D2 of Directive 2001/18/EC), if different from a similar release or placing on the market of the recipient or parental organism(s)**

30. **Potential environmental impact of the interaction between the GMHP and target organisms (if applicable), if different from that of the recipient or parental organism(s)**

31. **Possible environmental impact resulting from potential interactions with non-target organisms, if different from that of the recipient or parental organism(s)**

(a) Effects on biodiversity in the area of cultivation
(b) Effects on biodiversity in other habitats
(c) Effects on pollinators
(d) Effects on endangered species

C. INFORMATION RELATING TO PREVIOUS RELEASES

32. **History of previous releases notified under Part B of Directive 2001/18/EC and under Part B of Directive 90/220/EEC by the same notifier**

(a) Notification number
(b) Conclusions of post-release monitoring
(c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC)

33. **History of previous releases carried out inside or outside the Community by the same notifier**

(a) Release country
(b) Authority overseeing the release
(c) Release site
(d) Aim of the release
(e) Duration of the release
(f) Aim of post-releases monitoring
(g) Duration of post-releases monitoring
(h) Conclusions of post-release monitoring
(i) Results of the release in respect to any risk to human health and the environment

D. INFORMATION RELATING TO THE MONITORING PLAN — IDENTIFIED TRAITS, CHARACTERISTICS AND UNCERTAINTIES RELATED TO THE GMO OR ITS INTERACTION WITH THE ENVIRONMENT THAT SHOULD BE ADDRESSED IN THE POST-COMMERCIALISATION MONITORING PLAN
