SUMMARY INFORMATION FORMAT FOR PRODUCTS CONTAINING

GENETICALLY MODIFIED HIGHER PLANTS (GMHPs)

(see also Council Decision 2002/812/EC)

# **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 the 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

1. Release country:
2. Authority overseeing the release:
3. Release site:
4. Aim of the release:
5. Duration of the release:
6. Aim of post-releases monitoring:
7. Duration of post-releases monitoring:
8. Conclusions of post-release monitoring:
9. 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:**