PART 1

(COUNCIL DECISION 2002/813/EC)

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

In order to tick one or several possibilities, please use crosses (meaning x or X) into the space provided as (…)

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| **A. General information** |
| 1. Details of notification |
| *(a) Member State of notification* | Click here to enter text. |
| *(b) Notification number* | B/HU/ / [[1]](#footnote-1) |
| *(c) Date of acknowledgement of notification* | day / month / year |
| *(d) Title of the project* |
| Click here to enter text. |
| *(e) Proposed period of release* |  From day / month / year until day / month / year  |
| 2. Notifier |
| Name of institution or company |
| Click here to enter text. |
| 3. GMO characterisation |
| *(a) Indicate whether the GMO is a* |
| *viroid* | ( … ) |
| *RNA virus* | ( … ) |
| *DNA virus* | ( … ) |
| *bacterium* | ( … ) |
| *fungus* | ( … ) |
| *animal* |
| *mammals* | ( … ) |
| *insect* | ( … ) |
| *fish* | ( … ) |
| *other animal* | ( … ) |
| *specify phylum, class* | Click here to enter text. |
| *other, specify (kingdom, phylum and class)* | ( … ) |
| Click here to enter text. |
| *(b) Identity of the GMO (genus and species)* |
| Click here to enter text. |
| *(c) Genetic stability – according to Annex IIIa, II, A(10)* |
| Click here to enter text. |
| 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) | Click here to enter country code. |
| 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 | Click here to enter text. |
| 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 | Click here to enter text. |
| Notification number |  … / … / … / …  |
| 7. Summary of the potential environmental impact of the release of the GMOs |
| Click here to enter text. |

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| **B. Information relating to the recipient or parental organism from which the GMO is derived** |
| 1 Recipient or parental organism characterisation Indicate whether the recipient or parental organism is a: |
| *viroid* | ( … ) |
| *RNA virus* | ( … ) |
| *DNA virus* | ( … ) |
| *bacterium* | ( … ) |
| *fungus* | ( … ) |
| *animal* |
| *mammals* | ( … ) |
| *insect* | ( … ) |
| *fish* | ( … ) |
| *other animal* | ( … ) |
| *specify phylum, class* | Click here to enter text. |
| *other, specify* | ( … ) |
| Click here to enter text. |
| 2. Name |
| *(i) order and/or higher taxon (for animals)* | Click here to enter text. |
| *(ii) enus* | Click here to enter text. |
| *(iii) species* | Click here to enter text. |
| *(iv) subspecies* | Click here to enter text. |
| *(v) strain* | Click here to enter text. |
| *(vi) pathovar (biotype, ecotype, race, etc.)* | Click here to enter text. |
| *(vii) common name* | Click here to enter text. |
| 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 | ( … ) |
| Mediteranean | ( … ) |
| Boreal | ( … ) |
| Alpine | ( … ) |
| Continental | ( … ) |
| Macaronesian | ( … ) |
| (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 microorganism* |
| *water* | ( … ) |
| *soil, free-living* | ( … ) |
| *soil in association with plant-root systems* | ( … ) |
| *in association with plant leaf/stem systems* | ( … ) |
| *other, specify* | ( … ) |
| Click here to enter text. |
| *(b) If the organism is an animal: natural habitat or usual agroecosystem* |
| Click here to enter text. |
| 5. *(a) Detection techniques* |
| Click here to enter text. |
| 5. *(b) Identification techniques* |
| Click here to enter text. |
| 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: Click here to enter text. |
| 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* |
| Click here to enter text. |
| 8. Information concerning reproduction |
| *(a) Generation time in natural ecosystems* |
| Click here to enter text. |
| *(b) Generation time in the ecosystem where the release will take place* |
| Click here to enter text. |
| *(c) Way of reproduction* |
| Sexual ( … ) | Asexual ( … ) |
| *(d) Factors affecting reproduction* |
| Click here to enter text. |
| 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, specify* | ( … ) |
| Click here to enter text. |
| *(b) relevant factors affecting survivability* |
| Click here to enter text. |
| 10. *(a) Ways of dissemination* |
| Click here to enter text. |
| 10. *(b) Factors affecting dissemination* |
| Click here to enter text. |
| 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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| **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) others, specify* | ( … ) |
| Click here to enter text. |
| 2. Intended outcome of the genetic modification |
| Click here to enter text. |
| 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* |
| *plazmid* | ( … ) |
| *bacteriophage* | ( … ) |
| *virus* | ( … ) |
| *cosmid* | ( … ) |
| *transposable element* | ( … ) |
| *other, specify* | ( … ) |
| Click here to enter text. |
| *(b) Identity of the vector* |
| Click here to enter text. |
| *(c) Host range of the vector* |
| Click here to enter text. |
| *(d) Presence in the vector of sequences giving a selectable or identifiable phenotype* |
| Yes ( … ) | No ( … ) |
| antibiotic resistance | ( … ) |
| other, specify | ( … ) |
| Click here to enter text. |
| Indication of which antibiotic resistance gene is inserted |
| Click here to enter text. |
| *(e) Constituent fragments of the vector* |
| Click here to enter text. |
| *(f) Method for introducing the vector into the recipient organism* |
| *(i) transformation* | ( … ) |
| *(ii) electroporation* | ( … ) |
| *(iii) macroinjection* | ( … ) |
| *(iv) microinjection* | ( … ) |
| *(v) infection* | ( … ) |
| *(vi) other, specify* | ( … ) |
| Click here to enter text. |
| 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* | ( … ) |
| *(vi) macroinjection* | ( … ) |
| *(vii) other, specify* | ( … ) |
| Click here to enter text. |
| 6. Composition of the insert |
| *(a) Composition of the insert* |
| Click here to enter text. |
| *(b) Source of each constituent part of the insert* |
| Click here to enter text. |
| *(c) Intended function of each constituent part of the insert in the GMO* |
| Click here to enter text. |
| *(d) Location of the insert in the host organism* |
| *on a free plasmid* | ( … ) |
| *integrated in the chromosome* | ( … ) |
| *other, specify* | ( … ) |
| Click here to enter text. |
| *(e) Does the insert contain parts whose product or function are not known?* |
| Yes ( … ) | No ( … ) |
| If yes, specify: Click here to enter text. |

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| **D. Information on the organism(s) from which the insert is derived** |
| 1. Indicate whether it is a |
| *viroid* | ( … ) |
| *RNA virus* | ( … ) |
| *DNA virus* | ( … ) |
| *bacterium* | ( … ) |
| *fungus* | ( … ) |
| *animal* |
| *mammals* | ( … ) |
| *insect* | ( … ) |
| *fish* | ( … ) |
| *other animal* | ( … ) |
| *specify phylum, class* | Click here to enter text. |
| *other, specify* | ( … ) |
| Click here to enter text. |
| 2. Complete name |
| *(i) order and/or higher taxon (for animals)* | Click here to enter text. |
| *(ii) family name for plants* | Click here to enter text. |
| *(iii) genus* | Click here to enter text. |
| *(iv) species* | Click here to enter text. |
| *(v) subspecies* | Click here to enter text. |
| *(vi) strain* | Click here to enter text. |
| *(vii) cultivar/breeding line* | Click here to enter text. |
| *(viii) pathovar* | Click here to enter text. |
| *(ix) common name* | Click here to enter text. |
| 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, specify the following |
| *(a) to which of the following organisms:* |
| *human* | ( … ) |
| *animal* | ( … ) |
| *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) |
| Click here to enter text. |
| 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 to exposure to biological agents at work?  |
| Yes ( … ) | No ( … ) |
| If yes, specify |
| Click here to enter text. |
| 5. Do the donor and recipient organism exchange genetic material naturally? |
| Yes ( … ) | No ( … ) | Not known ( … ) |

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| **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 ( … ) |
| Specify: Click here to enter text. |
| *(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 ( … ) |
| Specify: Click here to enter text. |
| *(c) is the GMO in any way different from the recipient as far as dissemination is concerned?* |
| Yes ( … ) | No ( … ) | Not known ( … ) |
| Specify: Click here to enter text. |
| *(d) is the GMO in any way different from the recipient as far as pathogenicity is concerned?* |
| Yes ( … ) | No ( … ) | Not known ( … ) |
| Specify: Click here to enter text. |
| 2. Genetic stability of the genetically modified organism |
| Click here to enter text. |
| 3. Is the GMO significantly pathogenic or harmful in any way (including its extracellular products), either living or dead? |
| Yes ( … ) | No ( … ) | Not known ( … ) |
| *(a) to which of the following organisms?* |
| human | ( … ) |
| animal | ( … ) |
| plants | ( … ) |
| other | ( … ) |
| *(b) give the relevant information specified under Annex III A, point II(A)(11)(d) and II(C)(2)(i)* |
| Click here to enter text. |
| 4. Description of identification and detection methods |
| *(a) Techniques used to detect the GMO in the environment* |
| Click here to enter text. |
| *(b) Techniques used to identify the GMO* |
| Click here to enter text. |

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| **F. Information relating to the release** |
| 1. Purpose of the release (including any significant potential environmental benefits that may be expected) |
| Click here to enter text. |
| 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, specify: Click here to enter text. |
| 3. Information concerning the release and the surrounding area |
| *(a) Geographical location (administrative region and where appropriate grid reference)* |
| Click here to enter text. |
| *(b) Size of the site (m2)* | Click here to enter size. m2 |
| *(i)actual release site (m2)* | Click here to enter size. m2 |
| *(ii) wider release site (m2)* | Click here to enter size. m2 |
| *(c) Proximity to internationally recognised biotopes or protected areas (including drinking water reservoirs), which could be affected* |
| Click here to enter text. |
| *(d) Flora and fauna including crops, livestock and migratory species which may potentially interact with the GMO* |
| Click here to enter text. |
| 4. Method and amount of release |
| *(a) Quantities of GMOs to be released* | Click here to enter text. |
| *(b) Duration of the operation* | Click here to enter text. |
| *(c) Methods and procedures to avoid and/or minimise the spread of the GMOs beyond the site of the release* |
| Click here to enter text. |
| 5. Short description of average environmental conditions (weather, temperature, etc.) |
| Click here to enter text. |
| 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 |
| Click here to enter text. |

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| **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 organism (if applicable) |
| *(i) order and/or higher taxon (for animals)* | Click here to enter text. |
| *(ii) family name for plants* | Click here to enter text. |
| *(iii) genus* | Click here to enter text. |
| *(iv) species* | Click here to enter text. |
| *(v) subspecies* | Click here to enter text. |
| *(vi) stain* | Click here to enter text. |
| *(vii) cultivar/breeding line* | Click here to enter text. |
| *(viii) pathovar* | Click here to enter text. |
| *(ix) ommon name* | Click here to enter text. |
| 2. Anticipated mechanism and result of interaction between the released GMOs and the target organism (if applicable) |
| Click here to enter text. |
| 3. Any other potentially significant interactions with other organisms in the environment |
| Click here to enter text. |
| 4. Is post-release selection such as increased competitiveness, increased invasiveness for the GMO likely to occur? |
| Yes ( … ) | No ( … ) | Not known ( … ) |
| Give details Click here to enter text. |
| 5. Types of ecosystems to which the GMO could be disseminated from the site of release and in which it could become established |
| Click here to enter text. |
| 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)* | Click here to enter text. |
| *(ii) family name for plants* | Click here to enter text. |
| *(iii) genus* | Click here to enter text. |
| *(iv) species* | Click here to enter text. |
| *(v) subspecies* | Click here to enter text. |
| *(vi) strain* | Click here to enter text. |
| *(vii) cultivar/breeding line* | Click here to enter text. |
| *(viii) pathovar* | Click here to enter text. |
| *(ix) common name* | Click here to enter text. |
| 7. Likelihood of genetic exchange in vivo |
| *(a) from the GMO to other organisms in the release ecosystem* |
| Click here to enter text. |
| *(b) from other organisms to the GMO* |
| Click here to enter text. |
| *(c) likely consequences of gene transfer* |
| Click here to enter text. |
| 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 stimulated natural environments (e.g. microcosms, etc.) |
| Click here to enter text. |
| 9. Possible environmentally significant interactions with biogeochemical processes (if different from the recipient or parental organism) |
| Click here to enter text. |

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| **H. Information relating to monitoring** |
| 1. Methods for monitoring the GMOs |
| Click here to enter text. |
| 2. Methods for monitoring ecosystem effects |
| Click here to enter text. |
| 3. Methods for detecting transfer of the donated genetic material from the GMO to other organisms |
| Click here to enter text. |
| 4. Size of the monitoring area (m2) | Click here to enter size. m2 |
| 5. Duration of the monitoring | Click here to enter text. |
| 6 .Frequency of the monitoring |
| Click here to enter text. |

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| **I. Information on post-release and waste treatment** |
| 1. Post-release treatment of the site |
| Click here to enter text. |
| 2. Post-release treatment of the GMOs |
| Click here to enter text. |
| 3. *(a) Type and amount of waste generated* |
| Click here to enter text. |
| 3. *(b) Treatment of waste* |
| Click here to enter text. |

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| **J. Information on emergency response plans** |
| 1. Methods and procedures for controlling the dissemination of the GMO(s) in case of unexpected spread |
| Click here to enter text. |
| 2. Methods for removal of the GMO(s) of the areas potentially affected |
| Click here to enter text. |
| 3. Methods for disposal or sanitation of plants, animals, soils, etc. that could be exposed during or after the spread |
| Click here to enter text. |
| 4. Plans for protecting human health and the environment in the event of an undesirable effect |
| Click here to enter text. |

1. The notification number is given by the Hungarian Authority [↑](#footnote-ref-1)