NOTIFICATION FORM INTRODUCTION INTO THE ENVIRONMENT: PLANTS

If you have any questions, please get in touch with the Dutch Office for Genetically Modified Organisms

("Bureau GGO") (E-mail: bggo@rivm.nl, telephone: [The Netherlands] 088 689 7099).

All data needed to complete this form will enter the public domain. Confidential information should be submitted at the same time in a separate appendix.

Specific contact details of the person responsible for the project (contact person) and the Environmental Safety Officer (ESO) must be supplied as indicated in Appendix 2. The submitted data in this appendix will be kept confidential and will thus not be made publicly available in accordance with the Personal Data Protection Act

This Notification Form may contain some questions that are not relevant to your application. You are requested NOT to answer any questions that are irrelevant to the activities for which you are applying.

Specific issues:

- Literature references have to be sent in with the application form.

- Confidential information has to be marked as such and has to be sent in separately.

- A SNIF B form has to be completed and has to be sent in as an electronic file in Word format.

INTERNET <http://bggo.rivm.nl>

ABBREVIATIONS

 GMO Genetically modified organism

 GMP Genetically modified plant

 IenW Dutch Ministry of Infrastructure and Water Management

 Law The Dutch Genetically Modified Organisms Decree

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# A. GENERAL INFORMATION

A.1 Title of the notification

 Answer:

A.2 Give a brief description of the subject of the notification

 Answer:

*[You are requested to give a descriptive title that specifies the aim of the activity in question. For example: Small-scale field trials with non-flowering genetically modified apple trees involving the introduction of a gene that codes for an antimicrobial protein (hordothionin). The aim of the genetic modification is to improve resistance to certain plant pathogenic fungi in apple trees]*

**A.3 Describe the activities involved**

Answer:

 *[Please give here a detailed description of the activities]*

A.4 In which year do you intend to start up the activities?

 Answer:

A.5 In which year do you expect to finish the activities?

 Answer:

A.6 Will consumption and/or feed experiments be part of the activities?

 Answer:

A.7 Has there been any hybridization carried out between the primary GMP and unmodified plants? If so, please state whether such hybrids are involved in the present activities.

 Answer:

A.8 COGEM issued an advice on October 30, 2017 (CGM/171030-01) on categories of field trials. To which category of field trials does your intended field trial belong?

 Answer:

A.9 Do you want to keep information confidential? If so, please specify how the release of the information would harm your competitive position.

 Answer:

*[Unless marked "Confidential", all the information contained in the notification and its appendices enters the public domain when the notification is publicly processed and the decision is published.*

*For the sections marked "Confidential", you are requested to give a summary that contains enough information to ensure a good general understanding of the notification. Furthermore, give a reason why certain information is marked "Confidential".]*

## AIM OF THE INTRODUCTION OF THE GENETICALLY MODIFIED PLANT INTO THE ENVIRONMENT

A.10 Specific aim of the activities involved in the notification

 Answer:

 *[For example "the specific aim of the project is to test the resistance to pathogen X"]*

A.11 General aim of the activities involved in the notification

 Answer:

*[Please specify the long-term aim of the trials here (e.g. to develop apple trees that are more resistant to fungal and bacterial diseases)]*

## LEGAL PERSON NOTIFYING FOR A CONSENT

 *[Please only give here the name of the legal person (same as legal entity) who is ultimately responsible for the activities performed]*

A.12 Name of the legal person

 Answer:

 Address

 Answer:

 Postal code and town

 Answer:

#  B. DATA FOR THE ORIGINAL PLANT SPECIES

## NAME OF THE ORIGINAL PLANT SPECIES

B.1 Common Dutch name

 Answer:

 Family

 Answer:

 Genus

 Answer:

 Species

 Answer:

 Subspecies

 Answer:

 Cultivar or cultivated line

 Answer:

## GEOGRAPHICAL DISTRIBUTION

B.2 In what systems (other than agricultural systems) does the original plant species occur in the Netherlands?

 Answer:

B.3 In what systems (other than agricultural systems) does the original plant species occur in countries surrounding the Netherlands?

 Answer:

B.4 In what kind of agricultural ecosystems is the original plant species cultivated?

 Answer:

B.5 In what other ecosystems (including agricultural systems) is the original plant species found?

 Answer:

## REPRODUCTION AND PROPAGATION

B.6 How does the plant reproduce in its natural habitat and which factors affect its reproduction?

Answer:

B.7 How is the plant propagated in the agricultural ecosystem where it is grown and which factors affect its propagation?

Answer:

B.8 What is the generation time of the plant in its natural habitat and which factors affect it?

Answer:

B.9 What is the generation time of the plant in the agricultural ecosystem where it is grown and which factors affect it?

Answer:

## SURVIVAL

B.10 What surviving parts or elements of the plant are formed and which factors affect them?

 Answer:

**B.11 How long do the surviving parts of the plant persist in her natural habitat and which factors affect this persistence time?**

 Answer:

**B.12** **How long do the surviving parts of the plant persist in the agricultural ecosystem where the plant is cultivated in the Netherlands and which factors affect this persistence time?**

 Answer:

B.13 What is the chance that the plant will survive outside the agricultural ecosystem in the Netherlands?

 Answer:

B.14 What is the chance that the plant will survive outside the agricultural ecosystem in countries surrounding the Netherlands?

 Answer:

## DISSEMINATION

B.15 What disseminating parts of the plant are formed and which factors affect them?

 Answer:

B.16 How long do the disseminating parts of the plant survive in her natural habitat and which factors affect this survival time?

 Answer:

B.17 How long do the disseminating parts of the plant survive in the agricultural ecosystem where the plant is cultivated in the Netherlands and which factors affect this survival time?

 Answer:

B.18 What is the chance that the plant will disseminate in the Netherlands?

 Answer:

B.19 What is the chance that the plant will disseminate in countries surrounding the Netherlands?

 Answer:

## HYBRIDISATION OR OUTCROSSING

B.20 Describe the method of pollination of the original plant species

 Answer:

[Is the plant pollinated by wind, insects or by self-pollination? If more than one type of pollination occurs, please give the ratio between them and specify the factors that affect the pollination.]

B.21 Is there a chance that the plant in question will hybridize or outcross with either cultivars or wild relatives in the Netherlands? If so, describe all possible accidental hybridizations.

 Answer:

B.22 Is there a chance that the plant in question will hybridize or outcross with either cultivars or wild relatives in countries surrounding the Netherlands? If so, describe all possible accidental hybridizations.

 Answer:

B.23 Has accidental hybridisation or outcrossing actually been observed in the Netherlands or in countries surrounding it? If so, describe the conditions under which it occurred.

 Answer:

## INTERACTIONS WITH OTHER ORGANISMS

B.24 Describe the known interactions between the plant in question and other organisms in the ecosystem where it is cultivated

 Answer:

[These interactions cover all possible symbiotic effects or harmful effects on insects, animals, plants and human beings]

## IDENTIFYING CHARACTERISTICS

B.25 Describe the characteristics that distinguish the original plant species from its relatives

 Answer:

# C. GENERAL INFORMATION ABOUT THE GENETIC MODIFICATION

## EARLIER OR OTHER MODIFICATIONS

C.1 Is the original plant species already genetically modified?

 Answer:

 *[Please state whether the plants or the plant species that are being genetically modified are already genetically modified in the past. If so, state whether the modification of the original plant was carried out in the Netherlands and under what consent Number.]*

## GENERAL DATA ON THE GENETIC MODIFICATION

C.2 What type of genetic modification has been used?

 Answer:

C.3 What is the intended result of the genetic modification?

 Answer:

C.4 Has the genetic modification been carried out in the Netherlands? If so, please give the relevant consent number.

 Answer:

## THE DNA THAT HAS BEEN USED FOR MODIFYING THE PLANT

C.5 Describe the organisation of the complete DNA construct that has been used for the modification process. Specify the origin of and the function assigned to all the components of the construct.

Answer:

*[Here is meant the complete construct that has been used to modify the plant in question. Therefore, if a vector has been used, you are requested to describe the origin of and the function assigned to both the vector and the insert, using a map. Please also specify whether there are any components that code for a harmful substance.]*

C.6 Does the construct code for one or more gene products that are functionally homologous to the gene products occurring naturally in the original plant species?

 Answer:

C.7 Does the construct contain sequences that code for toxins or allergens?

 Answer:

C.8 Does the construct contain sequences whose products are unknown?

 Answer:

# D. INFORMATION ABOUT THE GENETICALLY MODIFIED PLANT (GMP)

*[The data requested in the following items vary with the category of the field trials and are not equally relevant to all trials. For example, data on the number of copies of the insert or on the site and stability of the insert are essential for large-scale trials but not yet for category 1 trials.]*

## HISTORY

**D.1 Have there been activities carried out already with the genetically modified plant in question or with plants containing a similar genetic modification? If so, please describe these activities, together with their results.**

 Answer:

D.2 Has there been any hybridisation between the primary GMP and other genetically modified plants? If so, please state whether such hybrids are involved in the present activities.

 Answer:

## CHARACTERISTICS

D.3 Describe the new or modified characteristics of the genetically modified plant.

 Answer:

## INSERTION

D.4 Specify the sequences that have been introduced

 Answer:

D.5 Is the insert fully or partially present in the genetically modified plant? Please state how this was determined.

 Answer:

**D.6 How many copies of the insert are present in the plant?**

 Answer:

**D.7 Is the insert located in the nucleus or located extra nuclear?**

 Answer:

**D.8 Is the insertion stably present?**

 Answer:

D.9 Is the absence of the vector backbone in the genetically modified plant confirmed? If yes, supply the method used and the results.

 Answer:

## EXPRESSION

**D.10 In which tissues or in which developmental stages of the plant are the new or modified characteristics expressed?**

 Answer:

D.11 What is the level of expression in these tissues and during these developmental stages? Please also specify the method used to determine this.

 Answer:

## DIFFERENCES BETWEEN THE ORIGINAL PLANT SPECIES ON THE ONE HAND AND THE GMP (AND IF APPLICABLE ANY HYBRID OF IT) ON THE OTHER HAND

*[Please list here all differences the genetically modified plant and any possible accidental hybrid exhibit compared to the original plant species, with respect to the points mentioned in Section B above (containing data for the original plant species)]*

D.12 Way of reproduction or propagation and/or duration of reproduction or propagation?

 Answer:

D.13 Parts of the plant that survive and/or duration of survival?

 Answer:

D.14 Way of dissemination and/or duration of dissemination?

 Answer:

D.15 Pollination?

 Answer:

D.16 Outcrossing?

 Answer:

D.17 Biological containment?

 Answer:

D.18 Competitive characteristics?

 Answer:

D.19 Toxic or allergenic effects?

 Answer:

D.20 Other harmful effects?

 Answer:

D.21 Symbiotic characteristics?

 Answer:

D.22 Resistances and tolerances?

 Answer:

D.23 Interactions with target organisms?

 Answer:

D.24 Interactions with non-target organisms?

 Answer:

D.25 Interactions with the abiotic environment?

 Answer:

D.26 Does the genetically modified plant differ from the original plant species in other respects than those mentioned above?

 Answer:

D.27 Describe the techniques that can be used to distinguish the genetically modified plant from the original plant species

 Answer:

#  E. DATA ON THE INTRODUCTION OF THE PLANT INTO THE ENVIRONMENT

## LOCATIONS

E.1 How many locations are mentioned in the notification?

 Answer:

E.2.a. In what municipalities are the experimental fields located?

 Answer:

**E.2.b.** **Will there be an isolation distance employed? If yes, specify the distance.**

Answer:

The answers on the questions below will depend on the category of field trial and whether an isolation distance is required. Before answering the questions, you are advised to contact the GMO Office.

CATEGORY 1 FIELD TRIAL INCLUDING AN ISOLATION DISTANCE

E.3.a. Answer these questions for each location for the category 1 field trial for which an isolation distance is required.

1. Is the attention zone entirely situated in the area over which you have authority?

Answer:

If not, go to question E.3.a.2.

If so, go to question E.3.a.3.

1. Can agriculture\* take place within the attention zone over which you have no authority?

Answer:

*[Explanation: If this is the case, you are advised to examine before each growing season if agriculture can take place within the attention zone over which you have no authority. If that is the case, you are advised to enter into a written agreement with the person that has authority over those agricultural activities, implying that he will not cultivate the specific crop within the attention zone. As far as you have not entered into written agreements, you have to check every two weeks during the growing season if the attention zone is observed.*

*\* In case of an application with genetically modified trees for which an isolation distance is required, the cultivation of trees in the attention zone is indicated here].*

1. Maps of locations

Answer:

*Provide for each location a topographic (Topografische Dienst, scale of 1:25.000 or more detailed) and a cadastral map. The topographic map must be able to be photocopied. The maps must be in color and should also be supplied electronically, as pdf file. On these maps the following items must be clearly indicated:*

 *- The cadastral parcel or part of this parcel (in which the field trial is situated);*

 *- The attention zone;*

 *- The borders of the area over which you have authority;*

*- The possibility of agriculture within the attention zone over which you have no authority (if applicable).*

CATEGORY 1 FIELD TRIAL WITHOUT ISOLATION DISTANCE

E.3.b. Maps of locations

 Answer:

*Provide for each location a topographic (Topografische Dienst, scale of 1:25.000 or more detailed) and a cadastral map. The topographic map must be able to be photocopied. The maps must be in color and should also be supplied electronically, as pdf file. On these maps the cadastral parcel or part of this parcel (in which the field trial is situated) has to clearly be indicated.*

CATEGORY 2 OR 3 FIELD TRIAL

E.3.c Maps of locations

 Answer:

*Provide for each location a topographic (Topografische Dienst, scale of 1:25.000 or more detailed) and cadastral map. The topographical map has to be able to be photocopied. The maps must be in color and should also be supplied electronically, as pdf file.* *Provide a map in which the field trial site is indicated as a rectangle. The rectangle can have a 100 times larger size (maximum) than the requested location for the field trial (for example, if is applied for a field trial of 1 ha, an area with a maximum size of 100 ha can be indicated).*

E.4 How many locations will be effectively used for the environmental introduction in any given year?

 Answer:

E.5 Have the locations mentioned in E.1 above been used earlier for the introduction of GMPs into the environment?

 Answer:

 If yes, please specify the GMPs involved

 Answer:

 Are these locations still subject to monitoring obligations?

 Answer:

 If yes, please specify the corresponding consent number

 Answer:

E.6 Area of each location

 Answer:

E.7 Total area of all locations used in any given year

 Answer:

## ECOSYSTEM

E.8 Is the type of ecosystem where the GMP is to be introduced different from the one where the original plant species is normally cultivated?

 Answer:

 If so, in what respect?

 Answer:

E.9 What is the distance from officially recognized biotopes and officially protected areas that the GMPs might affect by outcrossing with wild relatives or by dissemination?

 Answer:

## DESIGN OF THE TRIALS AND THE INTRODUCTION OF THE GMP

E.10 Describe the experimental design of the trials

 Answer:

 *[Please outline the design and set up of the trials, mentioning the number of replications, potential border rows and any agricultural activities involved]*

E.11 Describe the treatment of the field prior to the introduction of the GMP

 Answer:

E.12 What is the number of GMPs to be introduced at each location and in total in each year?

 Answer:

E.13 What method or methods are used for the introduction of the GMP?

 Answer:

E.14 Describe the methods used to keep out unauthorized persons from the area

 Answer:

E.15 Describe the methods used to prevent other organisms from entering the area

 Answer:

E.16 If you have stated in A.6 that the GMPs are to be used for human and animal consumption trials, please specify here the design and nature of these tests

 Answer:

## TRANSPORT

E.17 Describe the mode of transport and packaging used for the GMPs and their parts

 Answer:

*[The packaging and transport must comply with the specifications laid down in Appendix 9 of the*

*Dutch Ministrial Regulation on Genetically Modified Organisms ("Regeling GGO")]*

## AFTER THE TRIALS

E.18 Describe the treatment of the introduction area after ending the trials, for example the removal of volunteers. Indicate for each treatment how this will take place

 Answer:

E.19 Describe the treatment of the GMPs itself, parts from the GMPs or of derived materials from the GMPs after ending the trials

 Answer:

E.20 Describe the type and amount of waste material produced

 Answer:

E.21 Describe the processing and disposal of the waste material formed

 Answer:

# F. EXPECTED EFFECTS OF THE GMP ON MAN AND THE ENVIRONMENT

 *This is the most important aspect of the whole Notification!!*

 *[Give a detailed assessment of the expected effects of the GMP on human health and the environment on the basis of the answers to the above questions and in accordance with Appendix II of EU Directive No. 2001/18/EC and the corresponding guidance notes of the European Commission (2002/623/EC). Please take into account any direct, indirect, immediate and delayed effects of the GMP on human health and the environment.*

*A risk analysis should be carried out for each GMP included in this notification, as well as for combinations of the GMPs, if any.*

*The risk analysis must cover the effects of the GMPs that are due to interactions between the GMPs and the environment(s) where they are introduced or where they may end up under the present activities. The effects in question are those which are relevant to safety to human health and the environment.*

*The risk analysis should include at least the aspects mentioned in Appendix 1 of this form. The risk analysis includes the following sections, which should be given in the same order as shown below:*

1. *List of the likely adverse effects;*
2. *Estimate of the likelihood of these effects actually taking place;*
3. *Evaluation of the risks and an estimate of the severity of the effects, based on Items 1 and 2 above. The severity can be estimated by comparing it with the severity assigned to similar risks, such as for example the effects that occur with non-GMPs in similar situations ('baseline principle');*
4. *If you have concluded in Point 3 that the risk is high, you are requested to examine what measures can be used to mitigate the risk (e.g. by removing the flower-heads or consider isolation distances);*
5. *Final conclusion of the risk analysis, stating the risk management measures that will be employed, and a conclusion as to the acceptability of the risks when these measures are put into operation.]*

*Please answer the following questions now:*

F.1 Indicate the potential direct, indirect, immediate and delayed adverse effects of the GMP in relation to human health and the environment

 Answer:

F.2 What is the likelihood that these adverse effects mentioned in F.1 will actually take place?

 Answer:

F.3 Estimate the risk of each adverse effect, taking into account the impact of any risk management measures taken

 Answer:

F.4 If a risk management measure is proposed in F.3, please describe this measure

 Answer:

F.5 Indicate which location-specific aspects are taken into account in the risk analysis. If there are no location-specific aspects, provide a risk analysis for the complete Dutch territory.

 Answer:

F.6 Estimate the overall risk for the intended activities with the GMP for human health and the environment

 Answer:

# G. PROPOSED MEASURES FOR CONTAINMENT AND RISK MANAGEMENT

G.1 What measures will be taken to prevent dissemination of the GMPs?

 Answer:

G.2 Describe all other measures taken to prevent effects of the GMPs on human health and the environment.

Answer:

 *[A measure that can be taken is e.g. the removal of the flower heads, so as to prevent any accidental hybridization or out crossing of the GMP. Other examples of such measures are given in Section 6 of 2003/701/EC, dealing with the reporting on field trials].*

# H. PROPOSED METHODS OF OBSERVATION DURING AND AFTER THE TRIALS

H.1 Draw up a monitoring plan, specifying how any effect of the GMPs on human health and the environment will be detected during and after the trials. Give a description of the methods used for this detection or observation.

 Answer:

*[You are requested to describe here all the aspects observed during and after the end of the field trials, together with the methods used for them. Please do this in the form of a monitoring plan, which should consist of two parts - a general and a specific one. The first should deal with the general aspects of the genetically modified plants, e.g. differences in their growth. The specific part should deal with the nature of the genetic modification, e.g. any effects on non-target insects in the case of Bt plants.*

*In every case the monitoring plan should detail the adverse effects of the GMP mentioned in Point F.1, in combination with the proposed measures of risk management set out in Point G.1. If you consider that no observation is necessary, please also mention this fact explicitly and give your reasons for it.*

 *The monitoring plan should also contain a description of e.g. the surface area of the field to which the observation refers, as well as the duration and frequency of the observation in question].*

# APPENDIX 1

## POINTS TO CONSIDER IN THE CONCLUSION ABOUT THE POSSIBLE ENVIRONMENTAL EFFECTS OF THE GMP INTRODUCTION

*(Directive 2001/18/EC Annex II under Point D.2 gives a number of aspects that should be used whenever applicable as the basis of the conclusions about the possible environmental effects of the introduction of the GMP into the environment. All these points should be taken into account when drafting the conclusions of the risk analysis.]*

1. Likelihood of the GMP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.

2. Any selective advantage or disadvantage conferred to the GMP.

3. Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMP and any selective advantage or disadvantage conferred to those plant species.

4. Potential immediate and/or delayed environmental impacts resulting from direct and indirect interactions between the GMP and target organisms, such as predators, parasitoids, and pathogens (if applicable).

5. Possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens.

6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMP and persons working with, coming into contact with or in the vicinity of the GMP release(s).

7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed.

8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).

9. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMP where these are different from those used for non-GMPs.

# APPENDIX 2

## PERSON RESPONSIBLE FOR THE PROJECT (CONTACT PERSON)

A.13 Title, initials and surname

 Answer:

A.14 Organization, Institute or Company

 Answer:

A.15 Department, Division or Section

 Answer:

A.16 Address for correspondence

 Answer:

A.17 Zip code and city

 Answer:

A.18 Telephone and fax number

 Answer:

A.19 E-mail address

 Answer:

## ENVIRONMENTAL SAFETY OFFICER (ESO)

A.20 Title, initials and surname

 Answer:

A.21. Organization, Institute or Company

 Answer:

A.22 Department, Division or Section

 Answer:

A.23 Address for correspondence

 Answer:

A.24 Zip code and city

 Answer:

A.25 Telephone and fax number

 Answer:

A.26 E-mail address

 Answer:

## SIGNATURE

Signed for the legal person Date:

Name:

ESO Date:

Name:

Person responsible for the Project Date:

Name: