2003/701/EC: Commission Decision of 29 September 2003 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council a format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market (Text with EEA relevance) (notified under document number C(2003) 3405)

Commission Decision

of 29 September 2003

establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council a format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market

(notified under document number C(2003) 3405)

(Text with EEA relevance)

(2003/701/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC[(1)], and in particular the second sentence of Article 10 thereof,

Whereas:

(1) With regard to the deliberate release of genetically modified organisms (GMOs) for any purpose other than placing on the market, Article 10 of Directive 2001/18/EC requires the notifier of such a release, to send the competent authority, after completion of a release, and thereafter, at any intervals laid down in the consent on the basis of the results of the environmental risk assessment, the results of the release in terms of any risk to human health or the environment, with, where appropriate, particular reference to any kind of product that the notifier intends to notify at a later stage.

(2) To date, most GMOs deliberately released in the Community pursuant to Part B of Directive 2001/18/EC are genetically modified higher plants (GMHP). It is necessary, therefore, with regard to those plants, to establish the format to be used by the notifier when presenting the results of the release to the competent authority. That format should reflect the need to enable the fullest possible exchange of relevant information, presented in a standardised and easily comprehensible manner. The format should be kept as general as possible so that, where appropriate, multi-sites, multi-annual releases or releases of several GMOs can be covered by a single report.

(3) Since genetic engineering is not restricted to higher plants, it will be necessary to establish formats for other types of GMOs, such as genetically modified (GM) animals (including GM insects), veterinary and medicinal products (containing or consisting of GMOs) or GM plants which could produce pharmaceutical products. Future developments may also make it necessary to adapt the report formats which have already been established.

(4) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 30 of Directive 2001/18/EC,

HAS ADOPTED THIS DECISION:

Article 1

For the purposes of presenting to the competent authority the results of the deliberate release into the environment of genetically modified higher plants (GMHP) pursuant to Article 10 of Directive 2001/18/EC, the notifier shall use the format set out in the Annex to this Decision, hereinafter "the report format".

Article 2

A report format shall relate to no more than one consent issued by the competent authority and shall be identified by a single notification number.

Article 3

1 For each notification number, a final report shall be delivered by the notifier, and final as well as intermediary post-release monitoring report(s) shall be delivered where appropriate. Both types of report shall be drawn up in accordance with the report format.

2 The final report shall be delivered after the last harvest of the GMHPs. Where no post-release monitoring is required for a notification, no further reports shall be necessary.

3 The final post-release monitoring report shall be delivered after completion of the post-release monitoring.

The competent authority shall, where appropriate, specify in the consent the duration of the post-release monitoring as well as the timetable for submission of the intermediary post-release monitoring reports.

4 The competent authority shall encourage notifiers to provide the report in an electronic form.

Article 4

The competent authority may require from the notifier additional information, in particular in the form of a logbook or interim reports, to be delivered in the course of the research programme, before the completion of a release.

Article 5

This Decision is addressed to the Member States.

Done at Brussels, 29 September 2003.
For the CommissionMargot WallströmMember of the Commission

ANNEX

FORMAT FOR THE PRESENTATION OF THE RESULT OF DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED HIGHER PLANTS IN ACCORDANCE WITH ARTICLE 10 OF DIRECTIVE 2001/18/EC

LOGO OF THE COMPANY OR RESEARCH INSTITUTE (OPTIONAL)

The report format shall be completed by the notifier.

The notifier shall fill in the report format according to the proposed form (tick boxes and/or, as far as possible, specific keywords to use in text fields).

The notifier shall illustrate as much as possible the reported data by means of diagrams, figures and tables. Statistical data could also be provided where relevant.

In the case of multi-sites, multi-events and/or multi-annual release(s), the notifier shall provide a general overview of the measures taken and effects observed for the full duration of the consent.

The space provided after each item is not indicative of the depth of the information required for the purposes of this report.

1. ***General information***

1.1. **European notification number: B/XX/YY/ZZ**

1.2. **Member State of notification:** .....

1.3. **Date of consent and consent number:** .....

2. ***Report status***

2.1. **Please indicate whether, according to Article 3 of the present Decision, the current report is:**

— the final report

— a post-release monitoring report

— ○ final ○ intermediary

3. ***Characteristics of the release***

3.1. **Scientific name of the recipient organism:** .....

3.2. **Transformation event(s) (acronym(s)) or vectors [1] used (if transformation event identity not available):**.....

3.3. **Unique identifier, if available:** .....

3.4. **Please provide the following information as well as the field(s) layout:**

Geographical location(s) (administrative region and, where appropriate, grid reference)	Size of the release site(s) [1] (m^2)	Identity [2] and approximate number of GM higher plants per event actually released (number of seeds/plants per m^2)	Duration of the release(s) (from…*(day/month/year)*…… *until*……*(d/m/y)*)

[1] Specify the size of the GM area and, where appropriate, the size of the non-GM area (e.g. non-GM border).
[2] Vectors used.

[1] In the case of small-scale field trials where several lines may be tested, the vectors used should be mentioned, which gives insight into the introduced traits and/or genetic elements. In the case of large(r)-scale trials, the number of events notified is limited to only one or a few events.

4. ***Any kind of product that the notifier intends to notify at a later stage***

4.1. **Does the notifier intend to notify the released transformation event(s) as product(s) for placing on the market under Community legislation(s) at a later stage?**

☐ Yes ☐ No ☐ Unknown to date

If yes, indicate the country(ies) of notification: .....

If yes, specify for which use(s):

— Import

— Cultivation (e.g. seed/planting material production)

— Food

— Feed

— Pharmaceutical use (or processing for pharmaceutical use)

— Processing for

  — Food use

  — Feed use

  — Industrial use

— Others (specify):

5. ***Type(s) of deliberate release(s)***

Please select the main type(s) (in boxes) as well as subtype(s) of the release(s). In the case of multi-sites, multi-events and/or multi-annual release(s), please provide a general overview of the type(s) of deliberate release(s) which has/have been carried out for the full duration of the consent. Please tick the appropriate type(s):

5.1. **Deliberate release(s) for research purposes** ☐

5.2. **Deliberate release(s) for development purposes** ☐

— Event screening

— Proof of concept ([2])

— Agronomic performances (e.g. efficiency/selectivity of plant protection product, yield capacity, germination capacity, crop establishment, plant vigour, plant height, susceptibility to climatic factors/diseases, etc.) (specify)

— Altered agronomic properties (e.g. disease/pest/drought/frost-resistance, etc.) (specify)

— Altered qualitative properties (prolonged shelf-life, enhanced nutritional value, modified composition, etc.) (specify)

— Stability of the expression

— Multiplication of lines

— Hybrid vigour study

— Molecular farming ([3])

— Phyto-remediation

— Others: ..... (describe) .....

5.3. **Official testing** ☐

— Variety registration on a national variety catalogue

  — DUS (= **D**istinctness, **U**niformity and **S**tability)

  — VCU (= **V**alue of **C**ultivation and **U**se)

— Others: (specify) .....

([2]) For example, testing the new trait under environmental conditions.
([3]) *'Molecular farming'* means the production of substances (for instance, proteins, pharmaceuticals) by plants, which have been genetically modified for a

5.4. **Herbicide authorisation** ☐

5.5. **Deliberate release(s) for demonstration purposes** ☐

5.6. **Seeds multiplication** ☐

5.7. **Deliberate release(s) for biosafety/risk assessment research** ☐

— Vertical gene transfer studies

  — Out-crossing with conventional crops

  — Out-crossing with wild relatives

— Horizontal gene transfer studies (gene transfer to micro-organisms)

— Management of volunteers

— Potential changes in persistence or dispersal

— Potential invasiveness

— Potential effects on target organisms

— Potential effects on non-target organisms

— Observation of resistant relatives

— Observations of resistant insects

— Others: (describe).....

5.8. **Other(s) type(s) of deliberate release(s):** ☐

(describe) .....

6. ***Method(s), result(s) of the release, management and monitoring measure(s) in respect of any risk to human health or the environment***

6.1. **Risk management measure(s)**

Please report the risk-management measures, which have been used to avoid or minimise the spread of the GMO(s) outside the site(s) of release, and in particular those measures

— which were not originally notified in the application,

— which were applied in addition to the conditions in the consent,

— which the consent required only under certain conditions (e.g. dry periods, flooding),

— for which the consent allowed the notifier a choice among different measures.

Tick the examples where appropriate:

6.1.1. *Before the sowing/planting:*

— Clear labelling of the GM seeds/planting material lots (distinct from other seeds/tubers/etc.) (describe)

— Segregation during the processing and transport of the seed/planting material (describe the method involved; provide example(s) of containment to prevent spillage during the processing and transport)

— Destruction of superfluous seeds/planting material (describe the method involved)

— Temporal isolation (specify)

— Rotation (specify the previous crop(s))

— Other(s): (specify).....

6.1.2. *During the sowing/planting activities:*

— Method of sowing/planting

— Emptying and cleaning of the sowing/planting machinery on the field of release

— Segregation during the sowing/planting (provide example(s) of containment to prevent spillage during the sowing/planting)

6.1.3. *During the period of release:*

— Isolation distance(s) (x metres)

  — from sexually compatible commercial plant species,

  — from sexually compatible wild relatives.

— Border row(s) (with the same crop or a different one, with a non-transgenic crop, x metres, etc.)

— Cage/net/fence/signpost (specify)

— Pollen trap (specify)

— Removal of GM inflorescences before flowering (indicate the frequency of the removal)

— Removal of bolters/relatives/hybrid partners (indicate the frequency of the removal, x metres around the GM field, etc.)

— Other(s): (specify): .....

6.1.4. *At the end of the release:*

— Harvest/destruction methods (of crop or parts of it)/other means (e.g. sampling and analysis of sugar beet pulp) (describe)

— Harvest/destruction before the ripeness of the seeds

— Effective removal of plant parts

— Segregated storage and transport of crop/waste (provide example(s) of containment to prevent spillage of collected seeds/crops/wastes)

— Clean up of machinery on the release site

— Destination of the waste, treatment of waste/surplus yield/plant residues (describe)

— Post-harvest treatment and cultivation measures on the release site (describe the method(s) for preparing and managing the release site at the end of the release, including cultivation practices)

— Other(s): (describe):.....

6.1.5. *Post-harvest measures*

Please indicate which measures were taken on the release site after the harvest:

Frequency of visits (average): .....

— Subsequent crop (specify)

— Crop rotation (specify)

— Fallow/no crop (specify)

— Superficial soil work/no deep ploughing

— False-sowing beds

— Control of volunteers (specify intervals and duration)

— Appropriate chemical treatment(s) (specify)

— Appropriate soil treatment(s) (specify)

— Others (specify)

6.1.6. *Other(s) measure(s): (describe):*

6.1.7. *Emergency plan(s)*

Indicate:

(a) if the release proceeded as planned:

  — Yes

  — No (describe for which reason, e.g. vandalism, climatic conditions, etc.):……..

(b) if measures according to the emergency plan(s) (Article 6(2)(a)(vi) and Annex III.B of Directive 2001/18/EC) had to be taken:

  — No

6.2. Post-release monitoring measures

Due to the fact that the current report format can be used for the final and post-release monitoring report(s), the notifier is asked to clearly make the difference between both types of report through this section 2 of Chapter 6. Please indicate whether

— **the post-release monitoring plan will start** (in the case of a final report, after the last harvest of the GM higher plants),

— **the post-release monitoring plan is ongoing** (in the case of an intermediary post-release monitoring report),

— **the post-release monitoring plan has been completed** (in the case of the final post-release monitoring report),

— **no post-release monitoring plan has to be fulfilled.**

The results of this monitoring are meant to confirm or invalidate earlier assumptions in the risk assessment.

According to the aforementioned cases, please indicate which monitoring measure(s) will be/are/were taken and where (on the release site/near the site (e.g. on fields edges)). Please be aware that all post-release monitoring measures taken during the whole post-release period shall be indicated here.

Specify:

— Monitoring measures within site

Duration:

Frequency of visits (average):

— Observation of resistant relatives

— Observation of resistant insects

— Control of volunteers (specify intervals and duration)

— Monitoring of gene flow (specify)

— Appropriate chemical treatment(s) and/or soil treatment(s)

— Others (specify)

— Monitoring measures of adjacent areas

Duration:

Frequency of visits (average):

Area monitored:

— Observation of resistant relatives

— Observation of resistant insects

— Control of volunteers and/or monitoring of feral populations (specify intervals and duration)

— Monitoring of gene flow (specify)

— Appropriate chemical treatment(s) and/or soil treatment(s)

— Others (specify)

6.3. Plan for observation(s)/method(s) involved

In this section the observation plan and the methods used to collect the effects, which have to be reported under the next section (section 6.4), need to be specified. Any amendments or modifications to the plan as proposed in the application and the SNIF (4) part B need to be specified in detail.

During the time between the notification and the final report submission, new scientific insights or methods may be developed which cause a change in the methods used. In particular these modifications need to be specified under this section.

6.4. Observed effect(s)

6.4.1. *Explanatory note*

All results of the deliberate release(s) in respect of any risk for human health or the environment shall be stated, without prejudice to whether the results indicate that any risk is increased, reduced or remains unchanged.

The main objectives of the information given in this section are:

— to confirm or invalidate any assumption regarding the occurrence and impact of potential effect(s) of the GMO(s) which was/were identified in the environmental risk assessment,

— to identify effect(s) of the GMO(s) which was/were not anticipated in the environmental risk assessment.

The observed **effect(s)/interaction(s)** of the GMO(s)

— with respect to any risk to human health,

— with respect to any risk to the environment

shall be reported under this section.

Particular attention shall be drawn to unexpected and unintended effect(s).

Indications as regards the effects, that the notifier may have to report, are provided hereunder. The effects have obviously to be considered in the light of the crop, the new trait, the receiving environment as well as the conclusions of the environmental risk assessment, which is carried out on a case-by-case basis.

In order to structure the information and to facilitate an efficient search within the given information, the notifier shall use, as far as possible, specific keywords to fill in the text fields under Chapter 6, especially sections 6.4.2, 6.4.3 and 6.4.4. A most updated list of those specific keywords is available on the Internet at http://gmoinfo.jrc.it

6.4.2. *Expected effect(s)*

This section concerns 'Expected effects', that is to say, potential effects which were already identified in the environmental risk assessment of the notification and could therefore be anticipated.

Notifiers should supply data from the deliberate release(s) which validate the assumptions made in the environmental risk assessment.

6.4.3. *Unexpected effect(s)* ([5])

'Unexpected effects' refer to effects on human health or the environment, **which were not foreseen or identified in the environmental risk assessment** of the notification. This part of the report should contain any information with regard to unexpected effects or observations relevant for the initial environmental risk assessment. In case of any observed unexpected effects or observations, this section should be as detailed as possible to allow a proper interpretation of the data.

6.4.4. *Other information*

Notifiers are encouraged to supply information, which is outside the scope of the notification but which might be relevant to the field trials in question. This may also include observations of beneficial effects.

7. Conclusion

In this chapter, the notifier should specify the conclusions drawn and the measures taken or to be taken on the basis of the results of the release with regard to further release(s) and, where appropriate, make reference to any kind of product the notifier intends to notify at a later stage.

The information provided in this report is not considered confidential in accordance with Article 25 of Directive 2001/18/EC.

This does not prevent the competent authority from requiring additional information from the notifier, both confidential and non-confidential.

In the case of confidential data, it should be provided in an Annex to the report format, with a non-confidential summary or general description of these data, which will be made available to the public.

DATE:

(**1**) OJ L 106, 17.4.2001, p. 1.

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are outstanding changes not yet made to 2003/701/EC: Commission Decision. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.