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

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/CZ/16/01**

1.2 Member State of notification: **Czech Republic**

1.3 Date of consent and consent number: **02.06.2016, 23920/ENV/16**

2. Report status

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

☒ final report

☐ a post-release monitoring report
☐ final ☐ intermediary

3. Characteristics of the release

3.1 Scientific name of the recipient organism: ***Glycine max***

3.2 Transformation event(s) (acronym(s)) or vectors[1] used (if transformation event identity not available): **LTB gene coding for E.coli protein under glycinine promoter**

[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 introduce traits and/or genetic elements. In the case of large(r)-scale field trials, the number of events notified is limited to only one or a few events.

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 release site(s)[2] (m^2)	Identity[3] and approximate number of GM higher plants per event actually released (number of seeds/plants per m^2)	Duration of the release(s) (from (d/m/y) until (d/m/y))
Region: Praha; Locality: Lysolaje	**2017** 6 m^2	Line 157 12 plants, planting density: 50 cm x 35 cm	15.06.2017 until 09.11.2017
Region: Praha; Locality: Lysolaje	**2018** 10 m^2	Line 157 30 plants, planting density: 50 cm x 35 cm	30.04.2018 until 16.10.2018
Region: Praha; Locality: Lysolaje	**2019** 10 m^2	Line 157 30 plants, planting density: 50 cm x 35 cm	30.05.2019 until 24.09.2019

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 (please specify):

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

Please select the main type(s) (in boxes) as well as the subtype(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 releases(s) which have been carried out for the full duration of the consent.

5.1 Deliberate release(s) for research purposes ☒

5.2 Deliberate release(s) for development purposes ☐

- ☐ Event screening

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

- ☐ Proof of concept[4]:
- ☐ Agronomic performances (specify):
- ☐ Altered agronomic properties (specific):
- ☐ Altered quantitative properties (specify):
- ☐ Stability of expression
- ☐ Multiplication of lines
- ☐ Hybrid vigour study
- ☐ Molecular farming[5]
- ☐ Phyto-remediation
- ☐ others (describe):

5.3 Official testing ☐

- ☐ Variety registration on a national variety catalogue
  - ☐ DUS (= Distinctness, Uniformity and Stability)
  - ☐ VCU (= Value of Cultivation and Use)
- ☐ others (specify):

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 ☐

- ☐ Verticle gene transfer studies
- ☐ Horizontal gene transfer studies (gene transfer to micro-organisms)
- ☐ Management of volunteers
- ☐ Potential changes in persistence or disposal
- ☐ 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) types(s) of deliberate release(s) ☐

[4] For example, testing the new trait under environmental conditions.
[5] „Molecular farming“ means the production of substances (for instance, proteins, pharmaceuticals) by plants, which have been genetically modified for a particular trait. “Molecular farming” could be defined as well as the production of plant-synthesized pharmaceuticals, plant-made pharmaceuticals, plant-based proteins production, etc.

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

6.1.1 Before sowing/planting:

☒ Clear labelling of the GM planting material lots (describe):

Soya plants in pots clearly labelled „Genetically modified organisms“.

☒ 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):

Soya plants were transfered separate from nontrangenic plants on the day of planting. The amount of plants was confirmed prior to planting according to the documentation.

☒ Destruction of superfluous seeds/planting material (describe method involved):

All plants for deliberate use were planted on the test plot.

☐ Temporal isolation (specify):

☐ Rotation (specify the previous crop(s)):

☐ others (specify):

6.1.2 During the sowing/planting

☒ Method of sowing/planting:

Plants were planted by hand.

☐ Emptying and cleaning of the planting machinery on the field of release:

☒ Segregation during planting (provide example(s) of containment to prevent spillage during planting):

Transport was conducted in separate labeled pots.

☐ others (specify):

6.1.3 During the period of release

☐ Isolation distance(s):
- ☐ from sexually compatible commercial plant species: **not applicable**
- ☐ from sexually compatible wild relatives: **not applicable**

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

☒ Cage/net/fence/signpost (specify):

Two warning signs have been placed „GMO – No Entry". The net was used to protect the plants.

☐ 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), describe:

Trials have been observed regularly during the vegetation period.

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):

The plants were harvested by hand. Separate plants were put into paper bags and transported to the neighbouring green house.

☐ Harvest/destruction before the ripeness of the seeds

☒ Effective removal of plant parts:

After harvest of the seeds the remaining parts of the plants have been autoclaved.

☒ Segregation storage and transport of crop/waste (provide example(s) of containment to prevent spillage of collected seeds/crop/wastes):

Harvested seeds were stored in plastic boxes inside the cold room.

☐ Clean up of machinery on the release site:

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

Autoclaved parts of plants were composted.

☒ 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 methods):

The plot was left without treatment till spring to allow the freeze destruction of possible weeding plants.

☐ other(s): describe:

6.1.5 Post-harvest measures

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

Frequency of visits (average):

Post-harvest monitoring was done in November and before setting a new field trial.

☒ Subsequent crops (specify):

No subsequent crop used except new soya plants.

☐ Crop rotation (specify):

☐ Fallow/no crop (specify):

☐ Superficial soil work/no deep ploughing:

☐ False-sowing beds

☒ Control of volunteers (specify intervals and duration): **Control of volunteers was done twice a year during all period of the field trials.**

☐ 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:

- if the release proceeded as planned:

  ☐ Yes:

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

- 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:

6.2 Post-release monitoring measures

Due to the fact that the current 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 capter 6. Please indicate whether:

☐ the post-release monitoring plan will start

☐ the post-release monitoring plan is ongoing

☒ the post-release monitoring plan has been completed

☐ 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 field edges)). Please be aware that all post-release monitoring measures taken during the whole post-release period shall be indicated here.

Specifiy:

☐ Monitoring measures within the 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

Specify the observation plan and the methods used to collect the effects, which have to be reported in section 6.4. Any amendments or modifications to the plan as proposed in the application and the SNIF[6] part B need to be specified in detail.

NB. 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.

The GM soya line has been cultivated under conventional agricultural practice. Trials have been observed regularly during the vegetation period.

[6] Summary notification information format (=SNIF)

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 anticipated in the environmental risk assessment.

The observed effect(s)/interaction(s) of the GMO(s) shall be reported:
- 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 an 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 sections “Expected effects”, that is to say, potential effects which were already identified in the environmental risk assessments 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.

The genetically modified line 157 shows the same characteristic in seed yield per plant as the parental variety Jack.

No differences regarding persistence in agricultural habitats or invasiveness in natural habitats compared to conventional soya variety was expected.

During field releases no effects in relation to effects on human or animal health or on the environment have been observed.

6.4.3 Unexpected effect(s)[7]

“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.

No unexpected effects have been observed.

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 might also include observations of beneficial effects.

No differences compared to control soya plants were found.

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 genetically modified soya line showed three-time higher seed yield compared to plants grown simultaneously in green house. The amount of soluble proteins in

[7] Without prejudice to Article 8 of Directive 2001/18/EC as regards handling of modifications or new information

seeds did not differ from values in seeds of the parental line. All seeds from the transgenic plants contained LTB protein coded by transgene. The field trials confirmed the possibility to produce the extraneous proteins from transgenic soya grown in field.

No effects on human or animal health or on the environment have been observed.

DATE: 9.9.2021