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

(COMMISSION DECISION 2003/701/EC)

LOGO OF THE COMPANY OR RESEARCH INSTITUTE (OPTIONAL)

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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/PL/04/02-02**
1.2. **Member State of notification: Poland**

1.3. **Date of consent and consent number**: **08-01-2007 DLOPiKgmo-431-01/02-02/2004/07**

2. ***Status sprawozdawczy***

2. Report status

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

— **the final report**

— a post-release monitoring report

— X final ☐ intermediary

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

Scientific name of the recipient organism: *Linum usitassimum var. Nike* and *Linum usitassimum var. Linola*

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))
Wrocław Karłowice parcel Nr 26, AM-13, area belongs to Wroclaw University	**400 m^2**	**Plasmid pBinAR**	**-from 21-04-2008 to 25-08-2008; -from 17-04-2009 to 14-08-2009, -from 22-04-2010 to 30-09-2010**
Malbork precincts 0014, Tragamin	**2 ha**	**Plasmid pBinAR**	**from 22-04-2010 to 12-09-2010**

[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:

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

Flax fibre enriched in PHB

Seeds and flax fibres enriched in antioxidants

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?**

ÎX Yes Î NO Î Unknown to date

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

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

5.2. **Deliberate release(t) 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) **altered FA composition in seeds, increase in antioxidant level in flax seeds, flax enriched in polymer PHB**
— 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).....

5.4 Herbicide authorisation ☐

5.4 Deliberate release(s) for demonstration purposes ☐

5.6 Seeds multiplication **X**

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) **No uncontrolled spreading of GMO as well as no unfavourable changes in environment was observed**

5.8 Other(s) types) 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 minimize 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) **each transgenic line was marked with label**
— 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 **In Wroclaw field sowing was performed with traditional method without using any machines; in Malbork it was performed with machine FAMAROL**

- 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)
- Other(s) (specify)

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) **In Wroclaw field was surrounded with 4m net and fence, field in Malbork was surrounded with 20m safety zone from other cultivation**
- 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): **in distance 1000m there is no other flax cultivation, and in 50m distance there is no other cultivation**

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):

1.1.1. 6.1.5. **Post-harvest measures**

Please indicate which measures were taken on the release site after the harvest:
Frequency of visits (average): **once a month in vegetation season**
- 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) **Mechanical removal of volunteers, disintegration and composting**
- Appropriate chemical treatment(s) (specify)
- Appropriate soil treatment(s) (specify)
- Others (specify) **After the harvest field was ploughed for depth 35cm to assure mineralization of plant remains**

6.1.6. ***Others) 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 plans) (Article 6(2)(a)(vi) and Annex III.B of Directive 2001/18/EC) had to be taken:

- NO

- Yes (describe):

6.2. **Post-release monitoring measures**

- **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**), YES**

- 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)

Soil samples (100g each sample) were taken from different parts of field where genetically modified flax plants were released. 5ml of 0,85% NaCl was added to each sample (1g), then vortex and cetrifugated. Supernatant was used to prepare microbiological growth. Then plasmid DNA was isolated from growing bacteria and it was used as template for PCR reaction with specific primers for 35S CaMV promoter (forward GAAAAGGAAGGTGGCTCCTA; reverse GGTCTTGCGAAGGATAGTGG). No product (35S CaMV promoter) was observed in all analysed samples in soil bacteria. In second reaction of PCR with primers specific for *nptII* (forward CCGACCTGTCCGGTGCCC; reverse CCGCCACACCCAGCCGGCC) no positive effect was also noticed.

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

6.4. **Observed effect(s)**

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.