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

1. GENERAL INFORMATION

1.1 European notification number

B/ES/09/11

1.2 Member State of notification

Spain.

1.3 Date of consent and consent number

Region of Navarra: Resolution 1240/2009, of June 1st, 2009, by the Regional Directorate-General of Environment & Water.

2. REPORT STATUS

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

FINAL report.

3. CHARACTERISTICS OF THE RELEASE

3.1 Scientific name of the recipient organism

Zea mays

3.2 Transformation event(s) [acronym(s)] or vector(s) used (if transformation event identity is not available)

59122 x 1507

3.3 Unique identifier, if available

DAS-01507-1 x DAS-59122-7

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)** (m^2)	**Identity and approximate number of GM higher plants per event actually released** (number of seeds/plants per m^2)	**Duration of the release**
Milagro (Navarra)	**153 m^2**	**59122 x 1507 inbred lines** **5 plants /m^2**	**Sowing: 06/02/2009** **Destruction: 11/13/2009**

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 at a later stage?

Import, feed and food use and processing in the EU were submitted under Regulation (EC) No. 258/97 (EFSA-GMO-NL-2005-15) and EFSA has adopted a positive scientific opinion on April 21st of 2009. The application for cultivation of 59122 x 1507 maize has been submitted under Regulation (EC) No. 1829/2003 (EFSA-GMO-NL-2005-28).

5. TYPE(S) OF DELIBERATE RELEASE(S)

5.1 Deliberate release(s) for research purposes

Evaluation of agronomic performance of the genetically modified inbreed lines and comparison with the conventional parental lines (not genetically modified), from which they derive.

5.2 Deliberate release(s) for development purposes

Not applicable.

5.3 Official testing

Not applicable.

5.4 Herbicide authorisation

Not applicable.

5.5 *Deliberate release(s) for demonstration purposes*

Not applicable.

5.6 Seeds multiplication

Characterization, self-fertilization and selection of inbred lines and hybrids, resultant of directed crossings.

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

Not applicable.

5.8 Other(s) type(s) of deliberate release(s)

Not applicable.

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)

6.1.1 Before the sowing/planting:

- It was confirmed a minimum isolation of 200 m from other commercial maize fields.
- Seeds of 59122 x 1507 inbred lines were packed and clearly labelled by qualified staff in our research centre in Peyrehorade (France), authorized to carry out confined operations with GM organisms (Nº 4593, April 6th 2006, Commission de Genie Genetique, France).
- Seed transport to the field was made the same day of the sowing, in the pre-prepared paper bags, labelled and closed in the laboratory, and classified according to the trial layout.

6.1.2 During the sowing/planting activities

- Seeds were transported in closed bags and their manipulation was made by qualified staff, warned about preventive measures to avoid any dissemination.
- Sowing was made with clean sowing machinery, avoiding spill in the soil.
- To avoid involuntary dispersion, once the sowing was finalized, the remaining seeds, which were stored in specific departments of the planting machine, were recovered, re-sealed and transported by qualified staff to the research centre in Peyrehorade (France). These surpluses, together with others from activities conducted in the research center are regularly destroyed by an authorized company.
- Before removing the machinery out of the field, it was checked that all the sowing cones had been cleaned.
- Competent Authorities were informed of the sowing dates with anticipation, and the planting were supervised later by officials from the Competent Authority.
- A minimum of eight lines of conventional maize were planted surrounding the trial, as pollen barrier.

6.1.3 During the period of release

- Trials have been monitored on several dates during the growing season, including visits by some experts and competent authorities. During the visits, besides the observations described in the studies, it has not been observed that the crop tends to turn into weed, or with higher susceptibility to pests and diseases that the conventional maize.

- No negative effect has been observed on “non target” organisms, on arthropofauna, or for the biodiversity in general.
- Pollen shed dates were notified in advance to the competent authorities.
- No incidences have occurred related to safety for human health and environment.

6.1.4 At the end of the release

- Authorities have been informed in advance on the harvesting dates and inspectors have supervised them.
- All the samples taken were tagged and bagged accordingly. The samples harvested for analytics purposes were bagged and tagged in the trial field. All the procedures were carried out under standard procedures, with full traceability, and watched over, guaranteeing that they could not end up into the human or animal food chain. The sample collection has been conducted under supervision of Competent Authority and in the presence of inspectors. The transport from the field to the research centre in Peyrehorade (France) has been subjected to a chain of custody provided to the Competent Authority.
- Trials were harvested with combine-harvester of cereals, modified with a mill to grind the grains and destroy their viability.
- The trials crop residues were destroyed with tillage, chopped with an offset disc harrow and then, buried or ploughed up with several blades passes.
- The combine and means of transport were cleaned before leaving the field.

6.1.5 Post harvest measures

The release site will be watched on during the year following the trials, and up to the maize flowering period, in order to destroy any eventual maize volunteers. The commercial crop planted in this field during the following season will be different from maize.

6.1.6 Other(s) measure(s) (Describe)

Not applicable.

6.1.7 Emergency plan(s)

All the biosafety measures planned to avoid accidental releases have been applied

Please indicate:

a) if the release proceeded as planned

The release proceeded as planned.

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]

They were not necessary.

6.2 Post-release monitoring measures

The monitoring results confirmed that 59122 x 1507 maize plants present the same risk to human and animal health, or the environment, as any conventional variety.

According to the cases mentioned, please indicate the monitoring measures adopted

Please specify:

Monitoring measures within site
Trial plots will be visited during the following growing season to destroy the volunteer maize plants, if any.

Monitoring measures of adjacent areas
Surrounding areas to the trials will be visited during the following growing season to destroy the germinated volunteer plants, if any.

6.3 Plan for observation(s)/method(s) involved
General observations on plant health, disease sensitivity and plant development; furthermore, unexpected and unusual characteristic has been recorded.

6.4 Observed effect(s)
Unexpected effects were not observed

6.4.1 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.
59122 x 1507 maize plants presented no risks to human or animal health, or the environment, different from those of conventional maize.

6.4.2 Expected effect(s)
59122 x 1507 maize plants developed normally and presented crop cycle and performance similar to their isogenic conventional counterparts.

6.4.3 Unexpected effect(s)
Unexpected effects were not observed

6.4.4 Other information
Not applicable

7. CONCLUSION

The deliberate release was carried out according to the notification proposal and in agreement with the conditions of consent in the Resolution 1240/2009, of June 1st, 2009, by the Directorate-General of Environment & Water of Navarra, guaranteeing safety to human and animal health and the environment.

All the measures to avoid the pollen and grain spread of the genetically modified plants outside the trial field were taken.

Trials have been executed as predicted. Behaviour of 59122 x 1507 maize inbred lines was similar to conventional maize and it has not been observed any negative effect on the human or animal health, or on the environment.