

FINAL REPORT OF THE RESULT OF DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED MAIZE Bt11 IN ACCORDANCE WITH ARTICLE 10 OF DIRECTIVE 2001/18/EC

NOTIFICATION B/ES/05/21



1. General information

1.1 European notification number: B/ES/05/21

1.2 Member State of notification: SPAIN

1.3 Date of consent and consent number: 16th May 2005 (B/ES/05/21)

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
o final o intermediary

3. Characteristics of the release

3.1 Scientific name of the recipient organism: *Zea mays*

3.2 Transformation event(s) (acronym(s)) or vectors¹ used (if transformation event identity not available): Bt11

3.3 Unique identifier, if available: SYN-BTØ11-1

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.

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 (m²)	Identity² and aproximate number of GM higher plants per event actually released (number of seeds/plants per m²)	Duration of the release(s) (from (day/month/year)...until ...(d/m/y))
Alforque (Zaragoza); Polígono 6; parcela 5	594 m ²	Maize Hybrid; 4290 plants in whole	From: (26/05/2005) until (07/11/2005) Planting-Harvest
Amposta Polígono 5; parcela 28A	594 m ²	Maize Hybrid; 4290 plants in whole	From: (27/05/2005) until (03/11/2005) Planting-Harvest
Deltebre Polígono 3; parcela 40	594 m ²	Maize Hybrid; 4290 plants in whole	From: (27/05/2005) until (02/11/2005) Planting-Harvest
Espuñes Polígono 30; parcela 326A	594 m ²	Maize Hybrid; 4290 plants in whole	From: (25/05/2005) until (23/10/2005) Planting-Harvest
Quinto de Ebro Polígono 16; parcela 110	594 m ²	Maize Hybrid; 4290 plants in whole	From: (25/05/2005) until (24/10/2005) Planting-Harvest
Sástago (Zaragoza); Polígono 34; parcela 148	594 m ²	Maize Hybrid; 4290 plants in whole	From: (26/05/2005) until (06/11/2005) Planting-Harvest
Torres de Segre Polígono CU-1; parcela 3209506	594 m ²	Maize Hybrid; 4290 plants in whole	From: (25/05/2005) until (24/10/2005) Planting-Harvest

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:..... ... France (C/F/96/05.10)

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

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

Please select the main type(s) (in boxes) as well as subtype(s) of the releases. In the case of multi-sites, multi-events and/or multi-annual release(s), please provide a general overview of the types 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

5.3 Official testing

- Variety registration on the National Variety Catalogue of Maize
 - VCU (=Value of **C**ultivation and **U**se)

5.4 Herbicide authorization

5.5 Deliberate release(s) for demonstration purposes

5.6 Seeds multiplication

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

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

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:

-Clear labeling of the GM seeds/planting material lots (distinct from other seeds/ tubers/ etc.)

All the seeds of the trial have been packed in an exclusive box for this trial, sealed and identified.

-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)

The transport has been done personally by the technician responsible for the sowing, just in the moment of that practice. No segregation took place.

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

Burial in the trial site

-Others (specify):

Temporary isolation. Due to the late sowing of the trial, there is estimated an isolation of the period of pollination of about 30 days.

6.1.2 During the sowing/ planting activities:

- Method of sowing/ planting:
Sowing was performed by pneumatic drill for agricultural experimentation.
- Emptying and cleanliness of the machinery of sowing in the field.
The drill is equipped with an automatic system to avoid mixtures, separating in a specific container all the seeds not sowed in the

corresponding plot. The remaining seeds of the sowing have been buried inside the perimeter of the trial.

The drill takes automatic equipment that informs about any mistake or accident during the sowing, an automatic book-keeper of the sowed grains, an automatic meter of dampness and a system auto cleaner to gather at the end of every plot any seed that had not been sowed.

- Others: (Specify).....

6.1.3 During the period of release:

- Isolation distance(s) (in meters)
 - from sexually compatible commercial plan species: 220 meters
 - from sexually compatible wild relatives: Sexually compatible wild relatives do not exist in Europe
- Border row(s) (with the same crop or a different one, with a non-transgenic crop, x meters, etc.):
 - With another maize: >220 m
 - The trial is surrounded with 8 rows of conventional maize.
- Pollen trap (specify):

These 8 rows of conventional maize act as pollen trap

6.1.4 At the end of the release:

Sowing was performed by pneumatic drill for agricultural experimentation, plot to plot. The grain of the crop has been buried inside the same perimeter of the trial.

The remaining plants have been incorporated into the soil.

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
- Control of volunteers (specify intervals and duration): In February, March, April and May there will be controlled any plant of maize that germinates inside the area of liberation of the trial.

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

6.1.7. Emergency plan(s)

Indicate:

(a) if the release proceeded as planned:

-Yes

(b) if measures according to the emergency plan(s) 8Article 6(2)(a)(vi) and Annex III.B of Directive 2001/18/EC had to be taken:

-No

6.2 Post-release monitoring measures

-The post-release monitoring plan will begin (in the case of the final post-release monitoring report, after the last harvest of GM High Plants) in November 2005, until July 2006.

-Monitoring measures within site

-Duration: from February to May

-Frequency of the visits (average): once a month

-Control of volunteers (specify intervals and duration): once a month during February, March, April and May of 2006.

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

During the visits to the trial site by the responsible technician (once a month during the culturing) has not been observed any anomaly in the development of the plants or any unexpected event that could indicate a risk.

6.4 Observed effect(s)

6.4.1 Explanatory note

- No adverse effects have been observed for the human health or the environment.

6.4.2 Expected effect(s)

Due to the resistance to the assault of the drill, the hybrids Bt have completed their normal development whereas the conventional hybrids have showed the symptoms of the assault of this plague of insects.

6.4.3 Unexpected effect(s)³

No unexpected effects have been observed.

6.4.4 Other information

³ Without prejudice to Article 8 of Directive 2001/18/EC as regards handling of modifications or new information.

7. Conclusion

The European Food Safety Authority (EFSA) adopted on 20th April 2005 its favourable opinion about the evaluation of the maize Bt11 for cultivation. This Opinion was published in *The EFSA Journal* (2005) 213, 1-33: *Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Referente C/F/96/05.10) for the placing on the market of insect resistant genetically modified maize Bt11, for cultivation, feed and industrial processing, under Part C of Directive 2001/18/EC from Syngenta Seeds (Question No EFSA-Q-2004-012)* Opinion adopted on 20 April 2005.

This Opinion can be consulted in the EFSA web site:
http://www.efsa.eu.int/science/gmo/gmo_opinions/922/gmo_opinion_ej213_bt11maize_cultivation_en1.pdf

The Bt11 maize has been evaluated for its security by numerous authorities in the world. It has been approved for its culture and for its use for human and animal consumption in: U.S.A., Canada, Argentina, Japan, South Africa, Uruguay and Philippines. Exclusively for human and animal consumption it has been authorized in Switzerland, Australia, New Zealand, Korea, Taiwan, Russia, China and the European Union (E.U.)

Consequently, any damage is not expected either during the accomplishment of these tests. The objective of the tests, as it was declared in the notification, was obtaining the registration of the variety in the National Catalogue of Varieties of Maize.

The results confirm the safety of the culturing for the environment and the agronomic adjustment of the studied hybrids.

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: December 14th 2005



Esteban Alcalde