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POSTRELEASE MONITORING REPORT

According to legal Order 606/2005 concerning the approval of the 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 in accordance to Art. 10 of Directive 2001/18/EC

S.C. Syngenta Agro SRL – Bt11xGA21 event – genetically modified insect resistant and herbicide tolerant maize – deliberate release into the environment for field trial purpose – FINAL POST-RELEASE MONITORING REPORT 2014

1. General information

1.1 European notification number: **B/RO/09/14**

Notification/Application: 2616/03.03.2009

1.2 Member State of notification: **Romania – National Agency for Environment Protection, National Competent Authority**

1.3 Date of consent and consent number: **No. 14 of the 2nd of June, 2009 – Beneficiary S.C. Syngenta Agro SRL**

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
|**X**| Final | | Intermediary

3. Characteristics of the release

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

3.2 Transformation event(s) (acronym(s)) or vectors[1] used (if transformation event identity not available): **Bt11xGA21 – insect resistant and herbicide tolerant maize**

3.3 Unique identifier, if available: **SYN-BTØ11-1xMON-ØØØ21-9.**

3.4 Please provide the following information as well as the field(s) lay-out:

Geographical location(s) (administrative region and, where appropriate, grid reference)	Size of the 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……(day/month/year)……until……(d/m/y)……)
Grabaț, Timiș County	**360 sqm / 1 hybrid**	**Bt11xGA21 – 6 plants per m²**	**28.05.2010-13.10.2010**
SCDA Lovrin, Timiș County	**360 sqm / 1 hybrid**	**Bt11xGA21 – 6 plants per m²**	**26.05.2010-09.09.2010**
Șeitin, Arad County	**360 sqm / 1 hybrid**	**Bt11xGA21 – 6 plants per m²**	**08.06.2010-26.10.2010**
Peregu mare, Arad County	**0 sqm**		
Cărpiniș, Timiș County	**0 sqm**		
Jimbolia, Timiș County	**0 sqm**		
Nădlac, Arad County	**0 sqm**		
CTS Dîlga, Călărași County	**0 sqm**		
CTS Râmnicu Sărat, Buzău County	**0 sqm**		
CTS Tecuci, Galați County	**0 sqm**		
CTS Mircea Voda, Brăila County	**0 sqm**		
CTS Târgoviște, Dâmbovița County	**0 sqm**		
CTS Satu Mare, Satu Mare County	**0 sqm**		

In Romania, genetically modified maize Bt11xGA21 has been tested in three locations, for the last time in 2010. In 2011-2014, **Bt11xGA21 maize event has not been tested in Romania**.

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

[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.

[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.

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):

In October, 2008, EFSA has officially published positive opinions on the safety of Bt11 maize cultivation.

In March, 2008, Syngenta received authorisation for placing on the market of products containing, consisting of, produced from GA21 maize pursuant to Regulation EC 1829/2003.

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

Please select the main type(s) (in boxes) as well as sub-type(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 | **X** |

5.2 Deliberate release(s) for development purposes | **X** |

Event screening
Proof of concept[4]
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) **Common agronomical performance observations.**
Improved agronomic properties (e.g. disease/pest/drought/frost resistance, etc) (Specify)
Improved qualitative properties (prolonged shelf-life, enhanced nutritional value, modified composition, etc) (Specify)
Stability of the expression
Multiplication of lines

[4] E.g. testing the new trait under environmental conditions.

Hybrid vigour study
Molecular farming[5]
Phyto-remediation
Others: **Study regarding soil insecticide treatments.**

5.3 Official testing | |
Variety registration on a national variety catalogue

DUS (= Distinctness Uniformity 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 |_|

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

Without prejudice to the specific environmental risk assessment as well as to the consent conditions, the notifier shall provide the following information in respect of any effect for human health or the environment. 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.

[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-synthesised pharmaceuticals, plant-made pharmaceuticals, plant-based proteins production, etc.

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) **Clear labelling of primary and secondary containers containing GM seeds („contains genetically modified organisms" and unique identifier code-SYN-BTØ11-1xMON-ØØØ21-9).**
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) **GM seeds were packed and sealed in special bags (primary and secondary containers) – sealed boxes. Seed delivery was carried out on the same day as seed import.**
Destruction of superfluous seeds/planting material (Describe the method involved) **Burial at 0.5 m depth**
Temporal isolation (Specify) **Sowing at one month delay.**
Rotation (Specify the previous crop(s)) **Commercial maize, genetically modified maize trial.**
Other(s): (Specify) ……..

6.1.2 During the sowing/planting activities:

Method of sowing/planting **Mechanical sowing/planting using hand planters, mechanical equipment.**
Emptying and cleaning of the sowing/planting machinery on the field of release **Cleaning of field equipment used during sowing/planting after each use. This operation was carried out within the GM trial perimeter.**
Segregation during the sowing/planting (Provide example(s) of containment to prevent spillage during the sowing/planting) **Each lot of seeds was clearly seperated using special bags („contains genetically modified organisms" and unique identifier code).**

Other(s): (Specify)…….

6.1.3 During the period of release:

Isolation distance(s) (x metres) from sexually compatible plant species, both wild relatives and crops **200 m**

Border row(s) (with the same crop or a different one, with a non-transgenic crop, x metres, etc) **12 border rows with conventional maize.**
Cage/net/fence/signpost (Specify) **Not applicable.**
Pollen trap (Specify) **12 border rows of conventional maize.**
Removal of GM inflorescences before flowering (Indicate the frequency of the removal) **Not applicable.**
Removal of bolters/relatives/hybrid partners (Indicate the frequency of the removal, x metres around the GM field, etc) **Not applicable.**
Other(s): (Specify) **The GM field trials were regularly visited, regular monitoring during growth and development stages.**

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) **Manual harvesting followed by field distruction by burial and soil incorporation of remaining plant material.**
Harvest/destruction before the ripeness of the seeds. **Not applicable.**
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 **Cleaning of field equipment used on the field. This operation was carried out within the GM trial perimeter.**
Destination of the waste, treatment of waste/surplus yield/plant residues (Describe) **Burial and soil incorporation of remaining plant material within the trial perimeter.**
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) **Chopping of remaining plant materials and soil incorporation.**
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) : **One visit per 2 months for 2 consecutive years.**
Subsequent crop (Specify):

Field trial location	2010/2011 Crop	2011/2012 Crop
SCDA Lovrin	GM trial/mustard	Wheat
Grabat (Timis)	Wheat	Wheat
Seitin (Arad)	Wheat	WOSR/Sunflower

Crop rotation (Specify) **Yes.**
Fallow / no crop (Specify)
Superficial soil work/no deep ploughing
False-sowing beds
Removal of volunteers (Specify intervals and duration) **Regular monitoring of the field trial site. One visit per 2 months for 2 consecutive years. No volunteer plants observed.**
Appropriate chemical treatment(s) (Specify)

Appropriate soil treatment(s) (Specify)
Others (Please 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
Yes (Describe):……..

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 afore-mentioned 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-**Two years following harvest in 2010.**
Frequency of visits (average): **3 visits/year (March-July).**
Observation of resistant relatives
Observation of resistant insects
Removal of volunteers (specify intervals and duration) **1 visit per 2 months (March-July) for two consecutive years according to permit conditions. No volunteer plants observed.**
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): **1 visit per 2 months (March-July) for two consecutive years.**
Area monitored: **including neighbouring fields.**
Observation of resistant relatives
Observation of resistant insects
Removal of volunteers (specify intervals and duration) **1 visit per 2 months for two consecutive years.**
Monitoring of gene flow (specify)
Appropriate chemical treatment(s) and/or soil treatment(s)
Others (please 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 SNIF6 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.

Visual monitoring on the field trial sites will record any unexpected or unusual events.

6.4 Observed effect(s)

6.4.1 Explanatory note

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).

[6] Summary Notification Information Format (= SNIF)

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)

The potential effects, which were already identified in the environmental risk assessment of the notification and could therefore be anticipated shall be addressed under this section.
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)[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 were observed during the release in the environment. No volunteers have been observed during the second year of post-harvest monitoring.

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. Conclusions

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.

No unexpected effects were observed during the release in the environment. No volunteers have been observed during the second year of post-harvest

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

monitoring. No negative effects to human health or the environment have been observed or reported.

3rd of December, 2014
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