PART 2

SUMMARY INFORMATION FORMAT FOR PRODUCTS CONTAINING GENETICALLY MODIFIED HIGHER PLANTS (GMHPs)

A. GENERAL INFORMATION

1. Details of notification

a) Member State of notification France
b) Notification number C/F/96.05.10
c) Name of the product (commercial and other names) "Name of the product" is interpreted as "type of product". The product is genetically modified maize (inbreds and hybrids), which is referred to hereafter as "Bt11 maize".
d) Date of acknowledgement of notification

2. Notifier

a) Name of notifier Syngenta Seeds SAS on behalf of Syngenta Seeds AG , Basel Switzerland and all affiliated companies
b) Address of notifier Syngenta Seeds SAS Chemin de l'Hobit 27 F-31 790 St. Sauveur France Telephone: 33(0) 562 799800 Fax: 33(0) 562 7999990
c) Is the notifier domestic manufacturer YES importer NO
d) In the case of an import the name and address of the manufacturer shall be given

3. General description of the product

a) Name of the recipient or parental plant and the intended function of the genetic modification The recipient or parental plant is *Zea mays* (field or sweet maize). The maize plant has been genetically modified to protect itself from attacks of insect corn borers (*Ostrinia nubilalis* and *Sesamia nonagrioides*).
b) Any specific form in which the product must not be placed on the market (seeds, cut-flowers, vegetative parts, etc.) as a proposed condition of the authorisation applied for The material can be used and handled as genetically modified maize, according to current legal requirements. However its uses in agriculture and/or processing are likely to be similar to those of non-GM maize grown for grain or silage purposes.
c) Intended use of the product and types of users The genetically modified Bt11 seed is anticipated to replace existing varieties of maize (field and sweet varieties) in conventional agriculture. This maize will be handled by farmers in agriculture, by employees in the grain industry, by employees in the plant breeding industry including subcontractors and consumed by animals (and humans after processing). The maize will be used as grain and silage to feed animals (such as chickens, cows and pigs). Maize will also be used as raw - material in the industrial transformation process (starch and semolina industries, distilling etc) and in the manufacture of products used for animal and human consumption, including sweetcorn.

d) Any specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for No, the genetically modified Bt11 seed is anticipated to replace existing varieties of maize in conventional agriculture. Bt11 seed will be labeled as 'genetically modified'.
e) If applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorisation applied for Not applicable
f) Any type of environment to which the product is unsuited The product is as suited to agricultural lands as any other non-modified maize.
g) Any proposed packaging requirements The seed will be packaged in the same manner as non-modified maize seed. Currently seed will be packed in units of 25,000 or 50 000 seed.
h) Any proposed labelling requirements in addition to those required by law A labelling proposal has been submitted in line with the Directive 2001/18/EC and is shown in Section 4 (Appendix1) of the updated information to support Dossier C/F/96.05.10.
i) Estimated potential demand (i) in the Community In 2000, maize production in the European Community was around 40.6 million tons. 2.9 million tons maize are imported into the European Community each year. (ii) in export markets for EC supplies There is no significant export out of Europe, of maize grain grown in Europe

j) Unique identification code(s) of the GMO(s) The unique identification code of Bt11 is: SYN-BT∅11-1

4. <u>Has the GMHP referred to in this product been notified under Part B of Directive 2001/18/EC and/or Directive 90/220/EEC?</u>

Yes √	No
(i) If *no*, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC	

5. <u>Is the product being simultaneously notified to another Member State</u> ?

Yes	No
(i) If *no*, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC	

Or

<u>Has the product been notified in a third country either previously or simultaneously</u>?

Yes √	No
If *yes*, please specify Bt11 has been approved for cultivation, food and feed use in USA, Canada, Argentina and Japan. It has been approved for food and feed use in Switzerland, South Africa, Australia and New Zealand. Bt11 field maize has been approved for import for food and feed use in the EU under Directive 90/220 (Notification C/GB/96/M4/1). The European Scientific Committee for Food has also recently (SCF/CS/NF/DOS/14 ADD2 Final :17April 2002) concluded that "*Bt11 sweet maize is as safe for human food use as its conventional counterparts*"	

6. Has the same GMHP been previously notified for marketing in the Community?

Yes √	No

If *yes*, give notification number and Member State

Syngenta Seeds (formerly Novartis Seeds) submitted an application concerning Bt11, as an insect tolerant crop to France (C/F/ 96 05 10) in 1996. The application was updated it in 1998 and in May 2002.

Syngenta Seeds (formerly Novartis Seeds) submitted an application to UK for Import and use of grain. The transformation event discussed in the application sent to UK, is the same event as discussed in this application, i.e. Bt11 maize. The authorization was granted on June 9, 1998 (implementation of the Commission Decision (98/292/EC) of April 22, 1998, published on May 5, 1998, OJ L131/28-29).

Syngenta Seeds (formerly Novartis Seeds) has also previously submitted a request for cultivation of Bt11 maize, as an insect tolerant crop, in the EU to Spain, in May 1998 (C/ES/98.02). This was subsequently withdrawn.

7. Measures suggested by the notifier to take in case of unintended release or misuse as well as measures for disposal and treatment

Maize is traditionally grown as an annual crop in the EU and cannot survive without human intervention. It is incapable of surviving as a weed due its highly effective domestication and inability to survive low temperatures for long periods of time. The genetic modification is not anticipated to alter these characteristics and unintended release of the genetically modified maize into the ecosystem will, in this respect, behave as non-modified maize.

Standard agricultural practices will be followed for waste disposal and treatment.

As it is of agronomic and economic importance to avoid where possible, and in all cases delay the onset of insect resistance to Bt11 maize, an insect resistance management plan will be associated with the Bt11 Maize.

B. NATURE OF THE GMHP CONTAINED IN THE PRODUCT

INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

8. <u>Complete name</u>

a) Family name Gramineae
b) Genus *Zea*
c) Species *mays*
d) Subspecies *mays* L
e) Cultivar/breeding line Bt11 and offspring derived from it
f) Common name Maize

9. a) Information concerning reproduction

(i) Mode(s) of reproduction

Maize reproduces sexually.

(ii) Specific factors affecting reproduction, if any

Maize is a wind-pollinated monoecious species. Staminate flowers and pistillate flowers are separated on the plant favouring natural out-crossing. Maize pollen dispersal is limited by its large size (0.1mm) and rapid settling rate. Life of a pollen grain is relatively short.

(iii) Generation time

Maize is an annual crop.

9. b) Sexual compatibility with other cultivated or wild plant species

The only sexually compatible wild or weedy species are *Tripsacum* and *Euchlaena* (teosinte) genera. Teosinte occurs only in Mexico and Guatemala; *Tripsacum* is found from Mexico to Brazil and in the eastern and western parts of the United States (Jugenheimer, 1976). Thus, maize has no wild or weedy related species in Europe and cannot cross-pollinate any other species (Niebur, 1992).

10. Survivability

a) Ability to form structures for survival or dormancy

Seeds are the only survival structures of maize.

b) Specific factors affecting survivability, if any

If seeds are dropped onto the soil during harvest, their survival over the winter will depend on soil moisture and temperature and on cultural practices, but survival is estimated not to exceed 24 months.

Maize cannot survive temperatures below $0^{o}C$ for more than 6 to 8 hours after the growing point is above ground (5 to 7 leaf stage). Damage from freezing temperatures, however, depends on the extent of temperatures below $0^{o}C$, soil condition, residue, length of freezing temperatures, wind movement relative humidity and stage of plant development.

Although the appearance of maize plants in rotational fields following the maize crop from the previous year is a common occurrence, maize volunteer plants are easily controlled by current agricultural practices, including cultivation and the use of selective herbicides (Niebur, 1992).

11. Dissemination

a) Ways and extent of dissemination

Maize can be disseminated through pollen or through seeds.

b) Specific factors affecting dissemination, if any

Pollen dispersal is influenced by wind and weather conditions.

Maize is an annual crop and the seed is the only survival structure. Natural regeneration from vegetative tissue in the field is not known to occur. Seed dissemination is dependent on mechanical harvesting, transport as well as wind damage which may cause some mature ears to drop to the ground and avoid harvest.

Maize cannot survive without human assistance and is incapable of surviving as a weed due to past selection in its evolution. In contrast to weedy plants, seed dispersal of individual kernels does not occur easily because of the structure of the ears of maize (Rissler and Mellon, 1993; Niebur, 1992).

12. Geographical distribution of the plant

Maize probably originated from Central America at least 5000 years ago**.**

Maize has a worldwide distribution; it is grown from 56°N Lat to 40 ° S Lat, below sea level of the Caspian plains up to 3000 m in the Andes Mountains and from semiarid regions (Russell and Hallauer, 1980). This explains why cultivars are so diverse regarding morphological and physiological traits. As man cultivates maize, it is found in arable lands. Maize is grown on 140 million hectares worldwide: of which 7 million hectares are in the EU.

13. In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts

Maize is normally grown in the EU.

14. Potentially significant interactions of the plant with other organisms in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms

Maize is the third largest crop in the world after wheat and rice. Maize covers about 140 million ha in the world; this plant has no detrimental effect on the environment. Moreover, maize has no wild relatives in Europe; therefore, it cannot hybridize with any other species in the EU.

Maize is not considered to be harmful or pathogenic to humans, animals or other organisms.

15. Phenotypic and genetic traits

Maize, a member of the grass family (gramineae) from the tribe *Maydeae* has been extensively studied (Niebur, 1992).

The maize plant is an annual plant with a chromosome number of 2n = 20. The male and female parts of the plants are spatially separated. The male flower is known as the tassel and is composed of spikelets, which are situated externally at the top of the plant. The female flower is found laterally on a branch from the central axis and consists of a thick axis, called the cob, on which pairs of spikelets are arranged in longitudinal rows.

INFORMATION RELATING TO THE GENETIC MODIFICATION

16. Description of the methods used for the genetic modification

The initial parental transformations of the maize lines were accomplished through the insertion of the plasmid pZO1502 into one elite line. Carrier DNA was not used in the transformation experiment.

In order to prevent the ampicillin resistance gene being transferred to the plant cell, the plasmid was digested prior to transformation with the restriction enzyme *NotI*.

This cleaves the plasmid in two fragments, one carrying the *Btk* and the *pat* genes, and another fragment with the ampicillin tolerance gene.

17. Nature and source of the vector used

The vector used for transformation was pZO1502. This is a derivative of pUC18 (Yanisch-Perron and Messing, 1985).

18. **Size, source [name of donor organism(s)] and intended function of each constituent fragment of the region intended for insertion**

Element	Size	Function	Donor
35S promoter	0.514 kb	triggers constitutive gene expression	CaMV
IVS6	0.472 kb	enhances protein expression	maize
cryIAb gene (Btk gene)	1.845 kb	encodes a truncated version of the full-length cryIAb gene	Bacillus thuringiensis subsp. kurstaki strain HD-1
nos terminator	0.27 kb	provides a polyadenylation site	Agrobacterium tumefaciens
35S promoter	0.42 kb	triggers constitutive gene expression	CaMV
IVS2	1.1.	enhances protein expression	maize
pat gene	0.558 kb	encodes for a phosphinothricine acetyl-transferase	Streptomyces viridochromogenes
nos terminator	0.22 kb	provides a polyadenylation site	Agrobacterium tumefaciens

INFORMATION RELATING TO THE GMHP

19. **Description of the trait(s) and characteristics which have been introduced or modified**

The product is transgenic maize, tolerant to the ECB. The tolerance mechanism to maize borers is accomplished by a Cry1Ab gene that has been introduced in the maize plants. The Cry1Ab produced within the maize plant is a truncated form of the δ-endotoxin protein isolated from the soil microorganism *Bacillus thuringiensis* ssp *kurstaki* HD-1. The tolerance mechanism to glufosinate ammonium herbicides is accomplished by expression of a *pat* gene that encodes an enzyme: phosphinotricin-N-acetyl transferase (PAT), capable of detoxifying the herbicide. The genes encoding the genetic traits were inserted into the genome of the maize plants and then, through traditional breeding methods, crossed into additional maize lines. The truncated Cry1Ab protein and the PAT protein are produced within maize tissues and, as demonstrated in greenhouse and field trials, protects the plants from feeding damage by first and second brood ECB larvae.

20. Information on the sequences actually inserted/deleted/modified

a) Size and structure of the insert and methods used for its characterisation, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP

The size and structure of the insert has been determined using Southern blot and sequencing analysis. Two gene cassettes have been introduced into Bt11: the CaMV 35S/intron/*Btk* HD-1/nos cassette of the *Btk* gene, and the CaMV 35S/intron/pat/nos gene cassette of the phosphinotricin (*pat*) gene.

No carrier or foreign DNA is remaining in the GMHP. In order to prevent the ampicillin resistance gene being transferred to the plant cell, the plasmid was digested prior to transformation with the restriction enzyme NotI. This cleaves the plasmid in two fragments, one carrying the *Btk* and the *pat* genes, and another fragment with the ampicillin tolerance gene.

The entire sequence has been sequenced and has been found to be 6.2kb. Information relating to the sequence has been submitted in the Dossier C/F/96.05.10 updated in 1998 and May 2002.

b) In case of deletion, size and function of the deleted region(s)

Not applicable to Bt11

c) Location of the insert in the plant cells (integrated in the chromosome, chloroplast, mitochondrion, or maintained in a non-integrated form), and methods for its determination

The inserted DNA is located on the short arm of chromosome 8. The insert is stably integrated into the plant chromosome and is inherited as a single dominant gene in a Mendelian fashion.

d) Copy number and genetic stability of the insert

Southern blot analysis has confirmed that the insert number is one. The insert is stably integrated into the plant chromosome and is inherited as a single dominant gene in a Mendelian fashion. Southern blot analysis has confirmed that the insert is stable over generations.

e) In case of modifications other than insertion or deletion, describe function of the modified genetic material before and after the modification as well as direct changes in expression of genes as a result of the modification

Not applicable to Bt11

21. Information on the expression of the insert

a) Information on the expression of the insert and methods used for its characterisation

Two genes are expressed within the Bt11 derived maize lines. A truncated Cry1Ab gene produces the Btk protein, which is responsible for the demonstrated tolerance to lepidopteran insect pests; and the *pat* gene that encodes the PAT enzyme, that provides tolerance to glufosinate ammonium herbicides.

The level of the Btk protein in various maize tissues has been determined by ELISA. Generally, higher levels were detected at the younger stages of tissue development. The level of Btk protein decreased as the plant reached full maturity and the tissues became senescent.

The level of the PAT enzyme in various maize tissues have been determined by ELISA. PAT protein was found in the leaf and tassel samples and to a lesser extent in the silk extracts. The levels of PAT protein found in the root, pollen and kernel were less than the level of detection (LOD).

b) Parts of the plant where the insert is expressed (e.g. roots, stem, pollen, etc.)

The highest Btk protein concentrations were found in the leaf tissue. The specific concentration of Btk protein (ngBtk protein/mg total protein) is similar for leaf, husk and stalk tissue but significantly lower in the kernel and pollen.

Detectable levels of PAT protein were found in the leaf and tassel samples. Some PAT protein was detected is silk extracts but the levels of PAT protein found in the root, pollen and kernel were below detection level.

22. Information on how the GMHP differs from the recipient plant in

a) Mode(s) and/or rate of reproduction

The seed production of the genetically modified maize lines and hybrids have been observed during the field trials conducted in France 1994 and 1995.

No difference was found between the genetically modified plants and the non-modified controls in terms of fertility.

b) Dissemination

Dissemination of maize plants occurs exclusively through seed. Maize cannot survive without human assistance due to past selection in its evolution (Galinat, 1988). Seed dispersal of individual kernels does not occur naturally because of the structure of the ears of maize. The introduced traits, insect-protection and herbicide tolerance, have shown no influence on reproductive morphology and hence no changes in seed dissemination would be expected. Bt11 maize has continued to show a polystichous female inflorescence (ear) on a stiff central spike (cob) enclosed in husks (modified leaves).

c) Survivability

Maize is highly adapted to agricultural systems. Maize disseminated into the environment is hardly able to grow because of the competition with other plants. The establishment of a spontaneous maize population is highly unlikely and has never been reported (Galinat, 1988). The genes introduced into Bt11 do not change this characteristic and the genetically modified maize behaves like non-modified maize.

d) Other differences

Bt11 differs from the recipient plant in that it is tolerant to lepidopteran insect pests and to glufosinate ammonium herbicides. This is the intended effect of the modification. No other differences have been noted.

23. Potential for transfer of genetic material from the GMHP to other organisms

Maize has no wild relatives in the EU. Dissemination of the trait by pollen is therefore only possible to other cultivated maize plants. If this happened it would only constitute a fraction of the harvest from the neighbouring fields, and is highly unlikely to result in establishment of the gene in the maize genetic pool since commercially grown hybrids are not used for seed.

There is no reported evidence to suggest that intact gene transfer occurs from a plant species to micro-organisms in the field situation. In addition, it has been shown that a soil bacterium does not take up non-homologous plant DNA at appreciable frequencies under natural conditions. (Nielson *et al*, 1997).

24. Information on any harmful effects on human health and the environment, arising from the genetic modification

The food safety of Bt11 maize has been evaluated in the framework of the dossier UK/C/96/M4/1, regarding import and food/feed use of Bt11 maize, as well as for the notification under the EU Novel Food Regulation. No harmful effects have been identified. The import of Bt 11 maize into the EU for food/feed has been approved (Commission Decision for authorization: 98/292/EC published in the Official Journal of the European Communities on May 5, 1998). The European Scientific Committee on Plants concluded that "*grain or products derived from imported grain harbouring Bt11 event would be safe for food use*"

Additionally the European Scientific Committee for Food has also recently (SCF/CS/NF/DOS/14 ADD2 Final :17April 2002) concluded that "*Bt11 sweet maize is as safe for human food use as its conventional counterparts*".

Ahl Goy *et al*. (1995) reported on studies with Bt protein on non-target organisms. The studies were conducted on several lepidopteran insects, on phytophagus and entomophagus insects, on honeybees and on earthworms. The conclusion of these studies was that the Cry1Ab protein is highly specific to certain lepidopteran pests and has no deleterious effects on non-target organisms.

In addition, a substantial number of field studies of non-target insect populations in Bt maize have been performed. To date no adverse effects of non-target invertebrates have been detected (ABSTC, 2002, Saxena and Stotsky 2001).

25. Information on the safety of the GMHP to animal health, where the GMHP is intended to be used in animal feedstuffs, if different from that of the recipient/parental organism(s)

The food and feed safety of Bt11 maize has been evaluated in the framework of the dossier UK/C/96/M4/1, regarding import and food/feed use of Bt11 maize and no harmful effects have been identified. The import of Bt 11 maize into the EU for food/feed has been approved (Commission Decision for authorization: 98/292/EC published in the Official Journal of the European Communities on May 5, 1998). The European Scientific Committee on Plants concluded that "*grain or products derived from imported grain harbouring Bt11 event would be safe for food use"*

Additionally the European Scientific Committee for Food has also recently (SCF/CS/NF/DOS/14 ADD2 Final :17April 2002) concluded that "*Bt11 sweet maize is as safe for human food use as its conventional counterparts"*.

26. Mechanism of interaction between the GMHP and target organisms (if applicable) , if different from that of the recipient/parental organism(s)

The modified maize does not interact with the environment in a different way than non-modified maize except for the tolerance to insects. A large number of field trials have been conducted since 1992 with the Bt11 maize line and progenies thereof. No significant difference has been observed between the Bt11 lines and non-modified control lines apart from protection to certain lepidopteran insects.

27. Potentially significant interactions with non-target organisms, if different from the recipient or parental organism(s)

The modified maize does not interact with the environment in a different way than non-modified maize except for the tolerance to lepidopteran insects. A large number of field trials have been conducted since 1992 with the Bt11 maize line and progenies thereof. No significant difference has been observed between the Bt11 lines and non-modified control lines apart from protection to certain lepidopteran insects.

Ahl Goy *et al*. (1995) has reported on studies with Bt protein on non-target organisms. The studies were conducted on several lepidopteran insects, on phytophagus and entomophagus insects, on honeybees and on earthworms. The conclusion of these studies was that the Cry1Ab protein is highly specific to certain lepidopteran pests and has no deleterious effects on non-target organisms.

In addition, a substantial number of field studies of non-target insect populations in Bt maize have been performed. To date no adverse effects of non-target invertebrates have been detected (ABSTC, 2002, Saxena and Stotsky 2001).

28. Description of detection and identification techniques for the GMHP, to distinguish it from the recipient or parental organism(s)

Bt11 maize can be identified by its tolerance to the herbicide glufosinate ammonium. In addition, an ELISA assay has been developed for the detection and quantification of the Btk protein in maize tissues.

The identification of the *Btk* and the *pat* genes can also be accomplished through a Southern blot analysis or PCR analysis. It would also be possible to distinguish the transgenic maize of Syngenta from other transgenic maize varieties and lines, based on the position of the transgene within the maize genome. This procedure utilizes Restriction Fragment Length Polymorphism (RFLP) probes.

A detection method for Bt11 has been supplied with the updated information accompanying this SNIF (see Section 4, Appendix 2).

INFORMATION ON THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE OF THE GMHP

29. Potential environmental impact from the release or the placing on the market of GMOs (Annex II, D2 of Directive 2001/18/EC), if different from a similar release or placing on the market of the recipient or parental organism(s)

An Environmental Risk Assessment has been completed and is submitted as in Section 2 of the updated information relating to the Dossier C/F/96.05.10.

In summary, no immediate or delayed adverse effects as a result of the direct and indirect interaction of Bt11 maize with the environment when compared to non modified maize have been identified.

30. Potential environmental impact of the interaction between the GMHP and target organisms (if applicable), if different from that of the recipient or parental organism(s)

The environmental impact of the genetically modified maize is not expected to differ from the environmental impact of non-modified maize. This statement is based on the experience gathered from extensive previous field releases and on the outcome of the environmental risk assessment (see Q29 above). As it is of agronomic and economic importance to delay the onset of insect resistance to Bt11 maize an insect resistance management plan will be associated with the Bt11 Maize.

31. Possible environmental impact resulting from potential interactions with non-target organisms, if different from that of the recipient or parental organism(s)

a) Effects on biodiversity in the area of cultivation An Environmental Risk Assessment has been completed and is submitted as in Section 2 of the updated information relating to the Dossier C/F/96.05.10. In summary, no immediate or delayed adverse effects as a result of the direct and indirect interaction of Bt11 maize with the environment when compared to non modified maize have been identified.
b) Effects on biodiversity in other habitats An Environmental Risk Assessment has been completed and is submitted as in Section 2 of the updated information relating to the Dossier C/F/96.05.10. In summary, no immediate or delayed adverse effects as a result of the direct and indirect interaction of Bt11 maize with the environment when compared to non modified maize have been identified.
c) Effects on pollinators An Environmental Risk Assessment has been completed and is submitted as in Section 2 of the updated information relating to the Dossier C/F/96.05.10. In summary, no immediate or delayed adverse effects as a result of the direct and indirect interaction of Bt11 maize with the environment when compared to non modified maize have been identified.
d) Effects on endangered species An Environmental Risk Assessment has been completed and is submitted as in Section 2 of the updated information relating to the Dossier C/F/96.05.10. In summary, no immediate or delayed adverse effects as a result of the direct and indirect interaction of Bt11 maize with the environment when compared to non modified maize have been identified.

C. INFORMATION RELATING TO PREVIOUS RELEASES

32. <u>History of previous releases notified under Part B of the Directive 2001/18/EC and under Part B of Directive 90/220/EEC by the same notifier</u>

a) Notification number

Country	Date	Number of locations	Permit number
Spain		1 location	B/ES/96.7
Spain		10 locations	B/ES/97.14
Spain		13 locations	B/ES/98.02
Spain		1 location	B/ES/99/27
Spain		2 locations	B/ES/00/04
Spain		4 locations	B/ES/01/06
Spain		1 location	B/ES/02/04
France		1 location	B/F/94.01.06
France		6 locations	B/F/95.01.03
France		13 locations	B/F/95.12.04
France		2 locations	B/F/96.01.09 (ICTIA program)
France		19 locations	B/F/ 95.12.04
France		2 locations	B/F/96.01.09 (ICTIA program)
France		31 locations	B/F/97.11.14
France		2 locations	B/F/96.01.09 (ICTIA program)
France		10 locations	B/F/99.01.02
France		2 locations	B/F/99.02.09 (ICTIA program)
France		1 location	B/F/99.01.02
France		2 locations	B/F/99.02.09 (ICTIA program)
France		2 locations	B/F/99.01.02
France		2 locations	B/F/99.02.09 (ICTIA program)
Italy		1 locations	B/IT/95.16
Italy		2 locations	B/IT/96.13
Italy		5 locations	B/IT/96.53
Italy		5 locations	B/IT/93.53
Portugal		4 locations	B/PT/98.1

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b) Conclusions of post-release monitoring

Previous field trials of Bt11 maize have not shown any differences between Bt11 and the isogenic controls in occurrence of volunteer plants in the following season. Bt11 has been grown commercially in the USA since 1997 with no reports of increased persistence or weediness.

c) Results of the release in respect to any risk to human health and the environment (submitted to the Competent Authority according to Article 10 of Directive 2001/18/EC)

Previous field trials of Bt11 maize could find no evidence for adverse effects on human health or the environment. Bt11 has been grown commercially in the USA since 1997 with no reports of adverse effects to human health or the environment.

33. History of previous releases carried out inside or outside the Community by the same notifier

a) Release country

A large number of field trials have been carried out inside and outside the European community. Bt11 maize has been grown on a commercial scale in the USA and Canada since 1997.

The Bt11 trait has been bred into field maize and edible (sweet) maize by Syngenta Seeds, in USA. Trials have been conducted with lines and hybrids, under different company names before the formation of Syngenta Seeds in November 2000. These trials have been carried out in the EU, USA, Canada, Chile, Uruguay, Argentina and South Africa.

b) Authority overseeing the release

Ministry of Agriculture, Ministry of Health or Ministry of Environment.

c) Release site

Various

d) Aim of the release Research and development trials
e) Duration of the release Varied dependant on the Consent
f) Aim of post-releases monitoring To confirm the assumptions of the Environment risk assessment and the management procedures for example in the control of volunteers.
g) Duration of post-releases monitoring Varied dependant on the Consent, typically 1 year.
h) Conclusions of post-release monitoring The field studies demonstrated the efficacy of the Bt11 maize against corn borers. Apart from the intended effect of the modification, no evidence for differences in Bt11 compared to non modified maize was observed, including persistence as volunteer plants in subsequent years.
i) Results of the release in respect to any risk to human health and the environment Previous field trials of Bt11 maize could find no evidence for adverse on human health or the environment. Bt11 has been grown commercially in the USA since 1997 with no reports of adverse effects to human health or the environment.

D INFORMATION RELATING TO THE MONITORING PLAN - IDENTIFIED TRAITS, CHARACTERISTICS AND UNCERTAINTIES RELATED TO THE GMO OR ITS INTERACTION WITH THE ENVIRONMENT THAT SHOULD BE ADDRESSED IN THE POST COMMERCIALISATION MONITORING PLAN

The Environmental risk assessment for Bt11 maize did not anticipate any adverse effects on human health or the environment. For this reason no case-specific monitoring has been recommended. However, as it is of agronomic and economic importance to avoid wherever possible, and in all cases delay insect resistance to Bt11, an Insect Resistance Management plan will accompany Bt11. A General surveillance Plan has also been submitted as part of the updated information (see Section 3, Appendix 2).

REFERENCES

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Galinat, W C. 1988. The Origin of Maize. pp. 1-31. In: G. F. Sprague and J.W. Dudley (ed.) “Maize and Maize Improvement”. 3rd ed. American Society of Agronomy. Madison, WI.

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