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

ROUNDUP READY COTTON LINE DERIVED FROM EVENT 1445

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LIST OF ABREVIATION

aad	DNA sequence that encodes for the aminoglycoside adenylyltransferase
AAD	Aminoglycoside adenylyltransferase
B.t.	*Bacillus thuringiensis*
B.t.k.	*Bacillus thuringiensis kumamotoensis*
bp	Base pairs
CaMV	Cauliflower mosaic virus
CBW	Cotton bollworm
Cry	Crystal protein, a diverse group of insecticidal proteins produced by *B.t.*
Cry1Ac	Cry protein with insecticidal properties directed against certain Lepidoptera
cry1Ac	DNA sequence that encodes for the protein, Cry1Ab
DNA	Deoxyribonucleic acid
E. coli	*Escherichia coli*
E.U.	European Union
ELISA	Enzyme-linked immunosorbent assay
fw	Fresh weight
GMHP	Genetically modified higher plant
GMO	Genetically modified organism
ha	Hectare
IPC	Insect-protected cotton
Kb	Kilobases
µg	Microgram
nptII	DNA sequence that encodes for the enzyme neomycin phosphotransferase II
NPTII	Neomycine phosphotransferase II
NTO	Non-target organism
OECD	Organisation for Economic Cooperation and Development
ORF	Open reading frame
PBW	Pink bollworm
PCR	Polymerase chain reaction
PV-GHBK04	Plasmid vector containing the genes of interest
RR	Roundup Ready
spp	Species
T	tonne
T-DNA	Transferred DNA
tRNA	Transfer RNA
U.S.	United States
USDA	United States Department of Agriculture

A. GENERAL INFORMATION

1. Details of notification

(a) Member State of notification : Spain

(b) Notification number : C/ES/97/01

(c) Name of the product (commercial and other names):

The name of the product is Roundup Ready®[1] cotton line derived from event 1445[2]. Varieties of cotton derived from this genetically modified line will be sold under the Roundup Ready® registered trade name.

This application under Directive 2001/18/EC is for the cultivation and marketing into the European Union of RRC 1445 and any progeny derived from crosses, for the purposes of production, importation, storage and processing to non-viable products for industrial, food and feed uses.

(d) Date of acknowledgement of notification : June 06, 1997

2. Notifier

(a) **Name of notifier :** Monsanto Company represented by Monsanto Europe S.A.

(b) Address of notifier :

Monsanto Europe S.A.	Monsanto
270-272 Avenue de Tervuren	800 N. Lindbergh Boulevard
B-1150 Brussels	St. Louis, Missouri 63167
BELGIUM	USA

(c) Is the notifier : domestic manufacturer : [ ]
importer : [X]

(d) In case of an import the name and address of the manufacturer shall be given

RRC 1445 will be manufactured in countries outside of the European Union where the appropriate approvals are obtained. The manufacturers are cottonseed companies with commercial licenses from Monsanto Company to sell cotton varieties containing the *cp4 epsps* gene.

3. General description of the product

(a) Name of the recipient or parental plant and the intended function of the genetic modification

To produce RRC 1445, a DNA sequence encoding i) the CP4 EPSPS protein which confers tolerance to glyphosate[3], ii) the AAD protein (aminoglycoside adenylyltransferase) which provides resistance towards spectinomycin or streptomycin for bacterial selection purposes and iii) the NPTII protein (neomycin phosphotransferase II) which provides resistance towards kanamycin for cotton

[1] Roundup Ready is a registered trademark of Monsanto LLC Technology
[2] Thereafter referred as RRC 1445
[3] Active ingredient of Roundup® herbicide

plant cell selection purposes, was inserted into cotton cells using *Agrobacterium tumefaciens* mediated transformation utilizing the plant expression vector, PV-GHGT07.

(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

RRC 1445 has been demonstrated to be equivalent to other cotton, apart from its tolerance to glyphosate and therefore cottonseed and processed products derived from RRC 1445 will be used in the same manner as any other cotton products.

(c) Intended use of the product and types of users

There are no specific differences when RRC 1445 is compared to traditional cotton except for its tolerance to glyphosate. RRC 1445 has been shown to be substantially equivalent, with exception of the introduced trait, to cotton currently in commerce and therefore, the proposed uses and the types of users for RRC 1445 are identical to those for traditional cotton.

(d) Any specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorisation applied for

RRC 1445 has been demonstrated to be substantially equivalent to other cotton, apart from its tolerance to glyphosate. No specific instructions or recommendations for storage of seeds, plants, or products derived from RRC 1445 are envisaged.

(e) If applicable, geographical areas within the E.U. to which the product is intended to be confined under the terms of the authorisation applied for

Cottonseed production in the E.U. is focused in Spain and Greece. Cottonseed products are utilized and processed in all member states of the European Union.

(f) Any type of environment to which the product is unsuited

Cottonseed derived from RRC 1445 will be used where traditional cottonseed is currently produced.

(g) Any proposed packaging requirements

RR cotton has been shown to be substantially equivalent to other cotton varieties. Therefore, RR cotton in the form of cottonseed and processed products will be used in the same manner as with other cotton and no specific packaging is foreseen.

(h) Any proposed labelling requirements in addition to those required by law

In accordance with the requirements of Directive 2001/18/EC, repealing Directive 90/220 on 17 October 2002, Monsanto will:

a) inform European and International traders of the approval for production into the European Union of RRC 1445,

b) provide all traders with the commercial name of the product and any agreed European and/or international unique identifier,

c) advise all traders, and other operators using the products, that RRC 1445 are subject to the traceability and labelling requirements of Directive 2001/18/EC.

d) In accordance with the requirements of Annex IV of Directive 2001/18, the product will be labelled with the following words "This product contains genetically modified organisms". Packages and bags containing the seeds will be identified as Roundup Ready to allow farmers to know they are purchasing a Roundup Ready variety. As for any other variety, all the usual pieces of information including variety name, seed quality, seed treatment, manufacturer's name and full address, will be given on the seed package.

(i) Estimated potential demand

(i) in the Community

In 2000, Spain and Greece produced respectively 3.14 T and 3.05 T per hectare and planted more than 90.6 and 413.6 thousand hectares, respectively. The corresponding cottonseed production is of 284,300 and 1,259,628 MT, respectively.

(ii) in export markets for EC supplies

Not relevant

(j) Unique identification code(s) of the GMO(s)

The unique identifier for RRC 1445, MON-01445-2, has been attributed based on the guidance for the designation of a unique identifier for transgenic plants developed by OECD's Working Group on Harmonisation of Regulatory Oversight in Biotechnology.

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

Yes [X] No [ ]

If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC

Not relevant.

5. ***Is the product being simultaneously notified to another Member State?***

Yes [ ] No [X]

If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC

See following sections.

OR

Has the product being notified in a third country either previously or simultaneously?

Yes [X] No [ ]

If yes, please specify

Australia, South Africa and the US.

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

Yes [ ] No [X]

I f yes, give notification number and Member State

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

RR cotton varieties will be marketed as cotton varieties in Europe or imported in mixture with other commodity cottonseeds. RR cotton varieties can only be legally marketed and used in the E.U. if they are certified to meet the criteria of uniformity, stability, and homogeneity for a variety according to the Organization of Economic Co-operation and Development (OECD) standards and registered in the European Common Catalogue. RR cotton varieties will also be the subject of a request for registration on the European Common Catalogue. No particular measures will be taken beyond those taken for other cotton varieties.

Cottonseed from RR cotton will be utilised in the same manner as other cottonseed products from cotton varieties produced or imported into E.U. These mixtures of bulk commodity cottonseed will be employed for food, feed, and industrial uses in the same manner as currently.

The measures for waste disposal and treatment for RRC 1445 products are the same as those for other cotton products.

B. NATURE OF THE GMHP CONTAINED IN THE PRODUCT

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

8. ***Complete name***

(a) Family name : Malvaceae

(b) Genus : *Gossypium*

(c) Species : *hirsutum*

(d) Subspecies : Not applicable

(e) Cultivar/breeding line : Coker 312

(f) Common name : cotton

9. **(a) Information concerning reproduction**

(i) Mode(s) of reproduction

Cotton is a perennial plant that is planted and harvested annually. Although natural crossing can occur, cotton is normally considered to be a self-pollinating crop. The pollen is heavy and sticky and transfer by wind is unlikely. It is transferred instead by insects, in particular, by various wild bees, bumble bees (*Bombus* spp.), and honeybees (*Apis mellifera*).

(ii) Specific factors affecting reproduction, if any

The range over which natural crossing occurs appears to be limited. Researchers traced movement of pollen by means of fluorescent particles and found that, even among flowers located only 50 to 60 meters from a cotton field which was surrounded by a large number of bee colonies to ensure ample opportunity for transfer of pollen, fluorescent particles were detected on only 1.6% of the flowers. For comparison, the isolation distances for foundation, registered and certified cottonseed in the U.S. are approximately 450 meters, 450 meters and 220 meters, respectively.

(iii) Generation time

The cultural cycle for cotton ranges from 120 to 200 growing days from seedling emergence to maturity. Rainfall, temperature, sunshine, and spring warming all impact optimal growth.

(b) Sexual compatibility with other cultivated or wild plant species

i) gene transfer to cultivated genotypes

In as much as similar cotton genotypes are fully compatible, any pollen that is transferred has the potential to produce a hybrid seed. The degree of out-crossing in a production field is strongly dependent upon the geographic location of the field (which means upon the crop ecology) and the kinds and numbers of insect pollen vectors. Bumble bees (*Bombus* spp.) and honey bees (*Apis mellifera*) are the most significant with the former being the most efficient pollinator.

Considerable work has been done on the degree of out-crossing between adjacent plants, rows and plots of cultivated cotton. Molecular techniques have been used to determine out-crossing from transgenic cotton plots buffered by cotton. It has been showed that no more than 6% out-crossing occurred to border rows and the percentage dropped rapidly in rows successively distant from the plot.

ii) gene transfer to wild plant species

The criterion of sexual compatibility greatly limits the potential of gene flow from cultivated *Gossypium* in the geopolitical boundaries of Spain, Greece or other countries of the European Union. No genera in the Gossypieae tribe occur naturally in these countries.

10. Survivability

(a) Ability to form structures for survival or dormancy

Cotton is a perennial plant that is harvested and planted annually and is not considered to have weedy characteristics. Seeds are the only survival structures. Cotton is not considered to have seed which can persist in the environment for long periods of time.

(b) Specific factors affecting survivability, if any

Cultivated cotton does not possess any of the attributes associated with long term survivability such as seed dormancy, long soil persistence, germination under diverse environmental conditions, rapid vegetative growth, a short life

cycle, high seed output, high seed dispersal or long distance dispersal of seeds. In most cotton growing areas of Europe some of the seed remaining in the field following harvest and cultivation may germinate in the autumn if conditions are favorable. The seeds not germinating are likely to rot and die. In cotton growing regions with mild and dry winters, such as in Spain and Greece, cottonseed may over-winter and germinate the following spring. These cotton volunteers can be easily controlled by current agronomic practices including cultivation and the use of appropriate herbicides such as atrazine, bromoxynil, glufosinate and paraquat.

11. Dissemination

(a) Ways and extent of dissemination

Cotton is a perennial plant that is harvested and planted annually. Dissemination occurs only by means of seeds. Genetic material can be disseminated by pollen movement.

(b) Specific factors affecting dissemination, if any

Seed dissemination is impacted by mechanical harvesting and transport as well as wind damage, which may cause some mature bolls to fall to the ground. Pollen dispersal is influenced by insect vectors, particularly, bumble bees (*Bombus* spp.) and honey bees (*Apis mellifera*), with the former being the most efficient pollinator.

12. Geographical distribution of the plant

Plants of the tribe Gossypiae originated in the tropics and subtropics. Except as a cultivated crop, they are essentially excluded from temperate climates. They also tend to be plants of the southern hemisphere.

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

In the E.U., cotton is commercially grown in Spain and Greece.

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

Cotton is known to interact with other organisms in the environment including a range of beneficial and pestiferous arthropods, fungal diseases and surrounding weed species. Cotton is cultivated in Spain and Greece and has a history of safe use in those countries. Cotton is not considered harmful nor pathogenic to humans, however the plant does produce gossypol and cyclopropenoid fatty acids, which are natural toxicants.

15. Phenotypic and genetic traits

The same as the recipient cotton cultivar Coker 312.

INFORMATION RELATING TO THE GENETIC MODIFICATION

16. Description of the methods used for the genetic modification

RRC 1445 was modified by incorporation of a DNA fragment derived from plasmid vector PV-GHGT07 into the maize genome using an *Agrobacterium tumefaciens* mediated transformation.

17. Nature and source of the vector used

The plasmid vector, PV-GHGT07, is a 12.032 Kb single border binary transformation vector. It contains well-characterised DNA segments required for selection and replication of the plasmid in bacteria as well as a right border for initiating the region of DNA (T-DNA) integrated into the plant genomic DNA.

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

Summary of the genetic elements intended for insertion in RR 1445

Sequence	Size (Kb)	Function
E9 3'	0.63	Poly A termination signal for *cp4 epsps* gene
cp4 epsps	1.36	Gene encoding CP4 EPSPS
CTP2	0.23	Transit peptide to direct CP4 EPSPS to chloroplasts
CMoVb	0.57	Promoter for *cp4 epsps* and *gox* genes
aad (3'')	0.79	Confers bacterial resistance to spectinomycin/streptomycin
NOS 3'	0.26	Poly A termination for *nptII* and *gox* genes
nptII	0.79	Plant selectable marker
P-35S	0.32	Promoter for *nptII*
ori-V	0.39	Origin of replication
ori-322	0.43	Origin of replication
gox	1.3	Gene encoding GOX
ctp1	0.16	Transitpeptide to direct GOX to chloroplasts

INFORMATION RELATING THE GMHP

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

The RRC 1445 produce the 5-enolpyruvylshikimate-3-phosphate synthase protein (CP4 EPSPS), derived from *Agrobacterium* strain *CP4*, which imparts tolerance to Roundup® herbicide and thus presents an alternative to current weed control practices, that promises both environmental and economic advantages.

N-phosphonomethyl glycine (glyphosate), the active ingredient of Roundup is an extremely effective broad spectrum, post-emergent herbicide. The primary mode of action of the herbicide is competitive inhibition of 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS), an enzyme in the shikimate pathway of aromatic amino

acid biosynthesis. Glyphosate is used as a foliar-applied, non-selective herbicide (Baird *et al.*, 1971; Malik *et al.*, 1989). It is highly effective against the majority of annual and perennial grasses and broad-leaved weeds. Glyphosate has no pre-emergence or residual soil activity. Furthermore, glyphosate is not prone to leaching, biodegradable and essentially non-toxic to mammals, birds and fish (Atkinson, 1985; Malik, *et al.*, 1989).

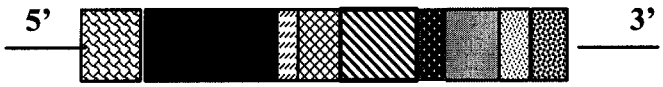
RRC 1445 is tolerant to topical applications of Roundup herbicide (up to the 4-leaf stage), and most weeds contacted by the spray are controlled. RRC therefore offers a tool for improved weed control. The use of cotton line 1445 can positively impact current agronomic practices in cotton, the benefits include (1) a reduction of potential for adverse effects to humans and the environment by replacement of currently used herbicides with Roundup; (2) an overall reduction in the amounts of herbicides used; (3) a reduction in the manufacturing, shipment and storage of chemical herbicides used on cotton; (4) an overall reduction in the exposure to workers to the herbicide and herbicide spray solution; (5) a reduction in the number of empty herbicide containers and amount of herbicide spray solution that must be disposed of according to applicable environmental regulations; (6) growers will replace high cost early post directed sprays that require special equipment with a simple application of Roundup herbicide, this provides a strong economic advantage in labour, timelines and management costs, of which both large- and small-scale growers will benefit; (7) a potential reduction of soil erosion, as Roundup can be used effectively in all conservation or no-tillage systems; (8) and finally, a possibility to implement 'Integrated Weed Management' practices and sustainable agricultural systems, that benefit the environment and are generally not possible when pre-plant or pre-emergent herbicides are used.

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

Southern blot analyses were conducted to characterise the inserted T-DNA. RRC 1445 contains one T-DNA insert which contains single copies of the full-length *cp4 epsps* gene, the *nptII* gene and the *aad* genes and is no larger than 6.1 Kb.

Schematic representation of the insert DNA in RRC 1445



E9 3'
(termination signal for *cp4 epsps* ORF)

500 Nucleotides

cp4 epsps ORF

CTP2
(direct CP4 EPSPS to chloroplast)

CMoVb
(promoter)

aad ORF

NOS 3'
(ends transcription and directs polyadenylation)

nptII ORF

P-35S
(promoter)

Ori-V
(origin of replication)

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

Not applicable

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

Southern blot analysis was conducted to confirm the location of the inserted DNA in the nuclear genome of RRC 1445.

(d) Copy number and genetic stability of the insert

The Southern blot analyses of genomic DNA from RRC 1445 show that the DNA transferred from PV-GHGT07 includes the CMoVb promoter, the *aad*, *nptII* and the *cp4 epsps* genes and a portion of the *ori-V* promoter. Evidence supporting that there is only one locus into which PV-GHGT07 DNA integrated into the genome of line 1445 and that there is a single copy of the *cp4 epsps* gene present in this line.

(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

21. Information on the expression of the insert

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

Levels of the expressed proteins CP4 EPSPS and NPTII were evaluated in leaf and seed tissues collected from six field locations during the 1993 U.S. growing season using ELISA and Western blot methods.

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

The levels of expression of the CP4 EPSPS for the tissues RRC 1445 comprised between 0.027-0.101 and 0.058-0.117 mg/mg FW, in leaves and seeds, respectively.

The levels of expression of the NPTII protein for the tissues of RRC 1445 are comprised between 0.019-084 and 0.004-0.011mg/mg FW, in leaves and seeds, respectively.

Neither the GOX protein nor the AAD proteins were detectable.

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

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

Data and information collected from field trials conducted in the United States demonstrated no significant morphological, growth or developmental differences between RRC 1445 and control cotton. The following characteristics were observed: seed germination; plant morphology; time to flowering, fruiting, boll formation; boll development and yield.

Based on those observations, no differences are anticipated in the reproductive capability of RRC 1445 when compared to the control cotton and therefore RRC 1445 should behave similarly to conventional cotton.

(b) Dissemination

i. pollen transfer to wild species

For gene flow to occur via normal sexual transmission certain conditions must exist: the two parents must be sexually compatible, their periods of fecundity must coincide, a suitable pollen vector must be present and capable of transferring pollen between the two parents and resulting progeny must be fertile and ecologically fit for the environment in which they find themselves.

Based upon these criteria, out-crossing to wild species is not considered possible in Spain, Greece and the other countries comprising the European Union as no other genera in the Gossypieae tribe are endemic to this geographic area.

ii. pollen transfer to cultivated genotypes

In as much as similar cotton genotypes are fully compatible, any pollen that is transferred has the potential to produce a hybrid seed. The degree of out-crossing in a production field is strongly dependent upon the geographic location of the field, which depends upon the crop ecology. The most important factors are the kinds and numbers of insect pollen vectors. Bumble bees (*Bombus* spp.) and honey bees (*Apis mellifera*) are the most significant with the

former being the most efficient pollinator. Typical out-crossing percentages for a number of locations in the U.S. cottonbelt range from 0 to 28%. Consequently, the transgenic material can be expected to be transferred to other cultivated genotypes over time.

While limited out-crossing to cultivated cotton (*Gossypium hirsutum*) can be expected, such out-crossing would not be expected to cause any adverse effects because cotton plants receiving the trait will behave in the same manner as RR cotton.

iii. transfer of genetic information to species to which it cannot interbreed

We are not aware of any other species within the countries of the European Union with which *Gossypium hirsutum* is able to successfully exchange pollen and produce viable hybrid plants. There is no evidence that plants can exchange genes with any other organisms in nature.

(c) Survivability

Studies have been performed to determine whether RRC 1445 improved survival and/or over-wintering characteristics which could increase the possibility of RRC 1445 to become a weed.

The results showed that the seed germination characteristics of RRC 1445 were equivalent to those of the control line. In addition RRC 1445 does not appear to possess an increased potential for over-wintering. Thus, this line should not have an increased risk for becoming a weed. In Europe cotton volunteers are not considered as a problem, due to ground frosts and/or soil cultivation techniques such as winter tillage. Cotton is not a competitive crop and therefore does not invade established ecosystems.

(d) Other differences

No other differences observed.

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

Based on the fact that pollen production and pollen viability as measured by yield and germination of progeny are unchanged by the genetic modification, the out-crossing frequency to other cotton varieties or to wild relatives (which are not present in the E.U.) is unlikely to be different for RRC 1445 when compared to other varieties. Also, none of the genetic elements introduced in the plant carries genetic transfer function.

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

An assessment of the human safety of the CP4 EPSPS and NPTII proteins was conducted based upon the extensive characterization of those proteins.

The human safety of the CP4 EPSPS and NPTII proteins has been established based upon the following considerations: (1) no amino acid sequence similarity to known toxins, and no immunologically relevant sequence similarity with known allergens, (2) rapid degradation under conditions which simulate mammalian digestive systems, (3) no indications of acute toxicity in mice administered CP4 EPSPS or NPTII protein by oral gavage, (4) very low dietary exposure, and (5) a history of safe use.

Finally, the nutritional equivalence of cottonseed from RRC 1445 has been established by compositional analysis.

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)

There is no difference between RRC 1445 and the recipient organism in terms of safety to animals.

An assessment of the human safety of the CP4 EPSPS and NPTII proteins was conducted based upon the extensive characterization of those proteins.

The human safety of the CP4 EPSPS and NPTII proteins has been established based upon the following considerations: (1) no amino acid sequence similarity to known toxins, and no immunologically relevant sequence similarity with known allergens, (2) rapid degradation under conditions which simulate mammalian digestive systems, (3) no indications of acute toxicity in mice administered CP4 EPSPS or NPTII protein by oral gavage, (4) very low dietary exposure, and (5) a history of safe use.

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

Not applicable, as the genetic modification confers herbicide tolerance.

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

EPSPS and NPTII are ubiquitous in nature and there is no known toxicity of these enzymes to any species. Cotton is a unique field crop in that mammals and other species which consume vegetation avoid feeding on the plant due to both gossypol in the plant and the morphology of the plant. The seed is within the boll and covered with lint. The seed will not be normally found in a lint-free condition in the field. Therefore, avian, fish, and other wildlife are not expected to be significantly exposed in nature.

Based upon these facts, we are able to conclude that these is no expected adverse affects to any species as a result of the release of these cotton lines into nature.

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

Southern blot or PCR techniques may be employed for the detection and identification of the inserted nucleotide sequences and ELISA for detection of the expressed CP4 EPSPS and NPTII proteins.

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)

The behaviour and characteristics of RR cotton plants have been studied since 1992 in a range of field environments including Puerto Rico, Mexico, South Africa, Argentina and the U.S. and no significant differences, compared to other cotton varieties, have been observed, apart from tolerance to glyphosate.

No adverse effects on the environment are expected from the production or import of Roundup Ready cotton grain or products derived from it.

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)

Not applicable.

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

No characteristics of Roundup Ready cotton lines derived from event 1445 which may cause an adverse effect could be identified. As Roundup Ready cotton lines derived from event 1445 are substantially equivalent to traditional, unmodified maize, except for the introduced glyphosate-tolerance trait and NPTII protein, all the agronomic practices currently used to grow cotton in the E.U. remain applicable for growing Roundup Ready cotton lines derived from event 1445 and no specific techniques for cultivation, management and harvesting are required

(b) Effects on biodiversity in other habitats

The interaction between Roundup Ready cotton lines derived from event 1445 and non-target organisms in the receiving agronomic and natural environment are no different from traditional cotton varieties, with exception of the potential exposure of non-target organisms to the introduced CP4 EPSPS and NPTII proteins expressed in Roundup Ready cotton lines derived from event 1445.

Based on i) the natural occurrence and history of exposure of non-target organisms to CP4 EPSPS and NPTII proteins, ii) the absence of plausible mechanism for biological activity toward non-target species, iii) the safety of these proteins, iv) the extensive experience of growing Roundup Ready cotton lines derived from event 1445, it is estimated the that the likelihood that CP4 EPSPS and NPTII protein could have any potential adverse on non-target organisms is negligible.

Therefore, the risk to non-target organisms, through their ecological interactions with Roundup Ready cotton lines derived from event 1445 is negligible.

(c) Effects on pollinators

No adverse effect on pollinators anticipated **(see 31.b)**

(d) Effects on endangered species

No adverse effect on pollinators anticipated **(see 31.b)**

C. INFORMATION RELATED TO PREVIOUS RELEASES

32. 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

(a) Notification number

Releases of RRC 1445 have been notified under Part B of the Directive 90/220/EEC in Greece (B/GR/97/03; B/GR/97/07; B/GR/98/07) and Spain (B/ES/97/12; B/ES/98/17; B/ES/00/02; B/ES/01/02).

(b) Conclusions of post-release monitoring

No differences were observed between RR cotton and other cotton plants.

(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)

Post-release general surveillance from environments provided no significant evidence that RRC 1445 is likely to pose any risk of adverse effects to human or animal health or to the environment.

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

(a) Release country

First year of experiment and commercialisation

Country	First year of experiment	First year of commercialisation
Argentina	1994	2001
Australia	1996	2000
Greece	1998	-
Mexico	1996	1999
South Africa	1997	2000
Spain	1997	-
U.S.	1992	1997

(b) Authority overseeing the release

Argentina: Secretary of Agriculture (SAGPyA) - CONABIA

Australia: previously GMAC and now OGTR (Office of Gene Technology Regulator)

Greece: Ministry of Environment and Ministry of Agriculture

Mexico: Agriculture and Health Ministries

South Africa: National Department of Agriculture

Spain: Comisión Nacional de Bioseguridad

USA: United States Department of Agriculture

(c) Release site

Argentina: cotton area, Northern part of Argentina

Australia: cotton growing regions of Queensland and New South Wales

Greece: County of Fthiotida, County of Larisa

Mexico: cotton growing area

South Africa: entire region where cotton is grown

Spain: Andalucía (Sevilla, Córdoba, Jaén, Cádiz)

USA: multiple field locations in the following States: California, Arizona, Texas, Louisiana, Mississippi, Arkansas, Georgia, Alabama, North Carolina

(d) Aim of the release

Argentina: Compare different hybrid phenotypes and yielding performanc

Australia: assess the performance: efficacy, yield, breeding

Greece: Adaptability to Greek conditions

Mexico: assess the performance

South Africa: general release approval for commercial sale and use

Spain: confirm use rates and use recommendations under Spanish conditions

USA: Agronomic and weediness assessments, and collect plant tissues for compositional and protein expression analyses; assess the agronomic performance: efficacy of the trait, yield, lint quality

(e) Duration of the release

Argentina: annual field trial permits. Field trials were conducted from 1994 to 2000.

Australia: ongoing

Greece: only during the 1998 cotton growing period

Mexico: one or two years

South Africa: conditional

Spain: one year (release repeated in 1998, 2000 and 2001)

USA: before commercial approval of RR cotton event 1445, experimental field trials were conducted from 1992 to 1996. In general the cotton was planted from February to June (depending on the location), and harvest was complete between Sept to Nov.

(f) Aim of post-releases monitoring

Argentina: Experimental stage (pre-commercial). Before commercial approval post-monitoring is to check for volunteer plants. No cotton was allowed to be grown in the same plot for three years

Australia: compliance with regulatory requirements

Greece: no post-release monitoring program

Mexico: no post-release monitoring program

South Africa: report back on any deviations form an efficacy perspective

Spain: confirm the overwintering and dissemination capabilities

USA: Before commercial approval, all field trials were monitored for volunteers for one year after final harvest, as part of the weediness assessment comparing RR and conventional cotton. Any volunteers were controlled by herbicides other than Roundup or cultivation practices.

There are no regulatory requirements for post-release monitoring of RR cotton in the US.

(g) Duration of post-releases monitoring

Argentina: three years

Australia: ongoing

Greece: not applicable

Mexico: not applicable

South Africa: on a continuous basis

Spain: one year

USA: no regulatory requirement for post-release monitoring

(h) Conclusions of post-release monitoring

Argentina: The RR trait does not change the volunteer potential of cotton.

Australia: no changes

Greece: not applicable

Mexico: not applicable

South Africa: after second season efficacy is intact – no crop damage with outstanding weed control

Spain: overwintering and dissemination risks are equivalent to those for conventional cotton varieties

USA : Pre-commercial monitoring: no difference in volunteers between RR and conventional cotton varieties. The RR trait does not change the volunteer potential of cotton.

(i) Results of the release in respect to any risk to human health and the environment

Argentina: no adverse effect was observed in comparison to conventional cotton varieties

Australia: no adverse effect

Greece: not such a conclusion was drawn, neither the design of the trials had such a target

Mexico: no adverse effect reported

South Africa: none

Spain: no evidence of any risk different from those of conventional cotton varieties

USA: RR cotton has been grown commercially in the US since 1997. No unusual plant pest characteristics have been reported for RR cotton, and no adverse effects on human health reported that are associated with production of RR cotton, and human consumption of cotton food products.

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

1. Confirmation that any assumptions regarding the occurrence and impact of potential adverse effects of the GMO or its use in the E.R.A. are correct.

The results of the environmental risk assessment (E.R.A.) of RRC 1445 (Annex II) show effectively zero overall risk arising from the placing on the market of this cotton relating to:

- Persistence or invasiveness
- Selective advantage
- Potential for gene transfer
- Impact on non-target organisms
- Effects on biogeochemical processes due to direct or indirect interactions with non-target organisms
- Changes in agricultural practice

Moreover, the risk assessment has demonstrated that RRC 1445 presents effectively zero risk to human and animal health relating to:

- Persons in proximity or contact with the release
- The consumption of products derived from RRC 1445

These conclusions having been reached on the basis of scientific data and analysis, rather than on the basis of assumptions, case-specific monitoring of RRC 1445 is not relevant.

2. Identification of the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the E.R.A.

The environmental and human health safety assessment for RRC 1445 did not identify any specific risks related to its placing on the market during production, storage, processing and other uses. Therefore the monitoring plan for RRC 1445 is focused on general surveillance for unanticipated, adverse effects.