

## SECTION 2

### SUMMARY NOTIFICATION INFORMATION FORMAT FOR THE PLACING ON THE MARKET (IMPORT) OF 281-24-236/3006-210-23 COTTON IN ACCORDANCE WITH DIRECTIVE 2001/18/EC

#### A. GENERAL INFORMATION

##### 1. Details of notification

###### (a) Member State of notification

The Netherlands.

###### (b) Notification number

C/NL/04/01.

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

The product described in this notification consists of cottonseeds derived from *B.t.* Cry1F-Cry1Ac cotton stack between events 281-24-236 and 3006-210-23, referred to as 281-24-236/3006-210-23 cotton will be sold under a commercial name defined before commercialisation. 281-24-236/3006-210-23 cotton has been, genetically modified to express Cry1F and Cry1Ac proteins, conferring resistance to certain lepidopteran insect pests under field conditions. The scope of the notification covers import of 281-24-236/3006-

210-23 cotton for use as any other cotton including industrial processing, but not for cultivation. A separate notification for the approval of food and animal feed uses of 281-24-236/3006-210-23 cotton and derived products, in accordance with regulation (EC) No 1829/2003, will be submitted in due course.

**(d) Date of acknowledgement of notification**

**2. Notifier**

**(a) Name of notifier**

This is a notification submitted by Agrigenetics, Inc. *d/b/a* Mycogen Seeds  
c/o DowAgroSciences LLC.

**(b) Address of notifier**

Dow AgroSciences Europe  
European Development Centre  
3 Milton Park, Abingdon  
Oxon OX14 4RN  
United Kingdom

Agrigenetics, Inc. *d/b/a* Mycogen Seeds  
c/o DowAgroSciences LLC  
9330 Zionsville Road  
Indianapolis, IN 46268-1054  
U.S.A.

**(c) Is the notifier****domestic manufacturer**

Mycogen is the developer of the technology and producer of 281-24-236/3006-210-23 cotton. This notification is for the import 24-236/3006-210-23 cottonseeds, including import of 281-24-236/3006-210-23 cottonseeds produced outside the EU.

**importer**

No.

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

Same as notifier.

**3. General description of the product****(a) Name of the recipient or parental plant and the intended function of the genetic modification**

Cotton *Gossypium hirsutum* is extensively cultivated and has a long history of safe use. Cottonseeds and derived products are not considered to have harmful characteristics, however, the plant produces gossypol and cyclopropenoids. The product consists of seeds derived from 281-24-236/3006-210-23 cotton, genetically modified to express Cry1F and Cry1Ac proteins, conferring resistance to certain lepidopteran insect pests under field

conditions, and PAT protein, conferring tolerance to glufosinate-ammonium during the selection stages of the genetic modification.

**(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**

281-24-236/3006-210-23 cotton has demonstrated to be equivalent to other cotton, a part from the protection conferred against certain insect pests. In addition, this notification is to import 281-24-236/3006-210-23 cottonseeds. Therefore, seed products of 281-24-236/3006-210-23 cotton will be used in the same manner as any other cotton products a part from cultivation. A separate notification for the approval of food and animal feed uses of 281-24-236/3006-210-23 cotton and derived products, in accordance with regulation (EC) No 1829/2003, will be submitted in due course.

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

Products from 281-24-236/3006-210-23 cotton will be used in a manner consistent with current uses of cottonseeds and derived products. This will include import of cottonseeds into the EU for storage and industrial processing. A separate notification for the approval of food and animal feed uses of 281-24-236/3006-210-23 cotton and derived products, in accordance with regulation (EC) No 1829/2003, will be submitted in due course.

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

The genetic modification in 281-24-236/3006-210-23 cotton is not expected to impact the existing industrial processing conditions used for cotton, which are well known and have a long history of use. The safety evaluation contained in this notification for the import of 281-24-236/3006-210-23 cotton provides further verification that no specific conditions of use and handling are required for 281-24-236/3006-210-23 cotton. Imported 281-24-236/3006-210-23 cotton products will be used, stored and handled as any other commercial cotton products. (See **Point A.3.h**) below for labelling of 281-24-236/3006-210-23 cotton.

**(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. Cottonseeds and derived products from 281-24-236/3006-210-23 cotton will be imported into the EU and will not be confined to any geographical areas within the EU. A separate notification for the approval of food and animal feed uses of 281-24-236/3006-210-23 cotton and derived products, in accordance with regulation (EC) No 1829/2003, will be submitted in due course.

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

This notification is for the import of 281-24-236/3006-210-23 cotton to the EU.

**(g) Any proposed packaging requirements**

The packaging, handling, and storage systems that are currently used for cotton will apply. Cottonseeds and processed products of 281-24-236/3006-210-23 cotton will be imported and packaged in the same manner as other cotton products. A separate notification for the approval of food and animal feed uses of 281-24-236/3006-210-23 cotton and derived products, in accordance with regulation (EC) No 1829/2003, will be submitted in due course.

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

Product information to indicate that genetic modification has been used in the development of 281-24-236/3006-210-23 cotton will be provided. A proposal for labelling of 281-24-236/3006-210-23 cotton has been developed in accordance with Annex IV of Directive 2001/18/EC (**Section 6**). This will enable the seed and seed by-products derived from 281-24-236/3006-210-23 cotton to be labelled in accordance with Directive 2001/18/EC when imported to the EU.

**(i) Estimated potential demand**

(i) in the Community

Europe has imported in the year 2001, 361.651 metric tonnes- (FAOSTAT Database, 2003). The 281-24-236/3006-210-23 cottonseeds are expected to be part of these imports.

(ii) in export markets for EC supplies

Cottonseeds are traded as a commodity and no specific demand for 281-24-236/3006-210-23 cotton should be expected from export markets for EC supplies.

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

In accordance with the OECD guidance for the designation of a unique identifier for transgenic plants (ENV/JM/MONO(2002)7), the unique identification code assigned to 281-24-236/3006-210-23 cotton is: **DAS-24236-5 x DAS-21Ø23-5.**

**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?**

No, see following sections.

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

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

No, a separate notification for the approval of food and animal feed uses of 281-24-236/3006-210-23 cotton and derived products, in accordance with regulation (EC) No 1829/2003, will be submitted in due course.

Or

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

Yes, an application for registration of 281-24-236/3006-210-23 cotton has been submitted to the US Environment Protection Agency (EPA). Also, an application for non-regulated status of 281-24-236/3006-210-23 cotton to the US Department of Agriculture (USDA) was submitted in January 2003, and a notification concerning foods derived from 281-24-236/3006-210-23 cotton to the US Food and Drug Administration (FDA) was submitted in March 2003.



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

No.

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

No specific measures, differing from those for any other commercial cottonseed, need to be taken in case of unintended release or misuse or for disposal and treatment. Any unintentional release or misuse of 281-24-236/3006-210-23 cotton would be limited and highly unlikely to have any adverse effect. Furthermore, and if necessary, such limited release can be controlled by current agronomic practices such as selective use of herbicides (with the exception of glufosinate-ammonium). This is based on the conclusions from the environmental risk assessment (e.r.a.) for the placing on the market of 281-24-236/3006-210-23 cotton in accordance to Annex II of Directive 2001/18/EC.

## **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 None
- (e) Cultivar/breeding line PSC355
- (f) Common name cotton

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

#### **(i) Mode(s) of reproduction**

Cotton is a perennial woody shrub, which is grown as an annual crop by planting it annually by seed. It reproduces sexually, is self-fertile, and generally self-pollinating. Cotton pollen is heavy and sticky and therefore not wind-borne under typical environmental conditions, thus, it is transferred by insects, such as bees, bumble- and honey- bees.

#### **(ii) Specific factors affecting reproduction, if any**

Cotton plants will grow and be productive on a wide variety of soils. They are most productive on fertile soil under hot weather and irrigated conditions if rainfall is deficient. *Gossypium hirsutum* is generally self-pollinating, but in the presence of suitable insect pollinators allows for limited cross-pollination. Even if suitable pollinators are present, distribution of pollen decreases considerably with increasing distance.

**(iii) Generation time**

Cotton plants cultural cycle ranges from 120 to 200 growing days covering the period from emergence of the seedling to maturity.

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

Cotton will intra-pollinate and transfer genetic material between cotton of similar genotypes. The extent of pollination will depend upon insect pollen vectors and geographical location. In addition, no genera in the Gossypaeae tribe occurs naturally in the EU preventing its gene transfer to wild relatives.

**10. Survivability****(a) Ability to form structures for survival or dormancy**

Cottonseeds, the only survival structures of cotton plants, are not able to persist in the environment for long periods of time.

**(b) Specific factors affecting survivability, if any**

Cottonseeds are not considered to be able to survive in the environment over long periods because they lack of dormancy, are not able to germinate under diverse conditions, short life cycle and high seed dispersal. In most cotton growing areas in Europe, the seeds which may remain in the soil may germinate in the autumn if conditions are right, otherwise, they are likely to rot and die. Cotton volunteers, can be easily controlled by current agronomic practices such as cultivation, and use of selective herbicides (atrazine, bromoxynil, paraquat and glyphosate).

## **11. Dissemination**

### **(a) Ways and extent of dissemination**

Cotton dissemination occurs only by means of seeds.

### **(b) Specific factors affecting dissemination, if any**

Mechanical harvesting, wind damage, which may cause some mature bolls to fall to the ground, and transport, are ways of disseminating cottonseeds. Regardless of these routes of dissemination, commercial cotton varieties cannot survive without human assistance.

## **12. Geographical distribution of the plant**

Plants of the *Gossypium* genus originated in different areas of the world, with centres of diversity in Australia Southern Asia, Africa and the World. Except as a cultivated crop, they are essentially excluded from temperate climates.

## **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**

Not applicable as 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 insects, birds, and mammals. It is susceptible to a range of fungal diseases and insect pests, as well as competition from surrounding weeds. Cotton is extensively cultivated and has a history of safe use, however, the plant produces gossypol and cyclopropenoid fatty acids which are toxicants.

**15. Phenotypic and genetic traits**

The same as the recipient cotton cultivar PSC355.

**INFORMATION RELATING TO THE GENETIC MODIFICATION**

**16. Description of the methods used for the genetic modification**

281-24-236/3006-210-23 cotton is a conventional cross between two transgenic lines transformed using the *Agrobacterium* method. The vectors used to transform the parental lines were PMYC3006 and pAGM281.

**17. Nature and source of the vector used**

Two different binary vectors were used for the genetic transformation of 281-24-236/3006-210-23 cotton parental lines 281-24-236 and 3006-210-23. As described in the notification, the intended insert of the line 281-24-236 consists of a linear T-DNA fragment, containing the *cry1F* and *pat* coding sequences together with the necessary regulatory components only. The

insert of the line 3006-210-23 consists of a linear T-DNA fragment, containing the *cry1Ac* and *pat* coding sequences along with the corresponding regulatory components.

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

The T-DNA of the binary vector pAGM281 contains the plant optimised coding sequences for the *cry1F* and *pat* genes, together with the necessary regulatory components to drive their expression.

The *cry1F* gene (3.45 kbp; origin: *Bacillus thuringiensis* subsp. *aizawai*) is under the control of the (4ocs)DeltaMas 2' promoter (0.61 kbp; origin: *Agrobacterium tumefaciens* pTi15955) and the bi-directional ORF25PolyA terminator (0.714 kbp; origin: *Agrobacterium tumefaciens* pTi15955). The function of the Cry1F protein in 281-24-236/3006-210-23 cotton is to provide resistance against certain lepidopteran insect pests such as the European corn borer.

The *pat* gene (0.55 bp; origin: *Streptomyces viridochromogenes* strain Tü494) is under the control of the ubiquitin promoter and sharing the ORF25PolyA terminator. The function of the PAT protein in 281-24-236/3006-210-23 cotton is to confer tolerance against glufosinate-ammonium during the genetic modification.

The T-DNA of the binary vector pMYC3006 contains the plant optimised coding- and regulatory sequences to enable the expression of for the *cry1Ac* and *pat* genes.

The *cry1Ac* gene (3.45 kbp; origin: *Bacillus thuringiensis* subsp. *kurstaki*) is under the control of the ubiquitin promoter and the bi-directional ORF25PolyA

terminator (0.72 kbp; origin: *Agrobacterium tumefaciens* pTi15955). The function of the Cry1Ac protein in 281-24-236/3006-210-23 cotton is to provide resistance against certain lepidopteran insect pests such as the European corn borer.

The *pat* gene (0.55 kbp; origin: *Streptomyces viridochromogenes* strain Tü494) is under the control of the (4ocs)DeltaMas 2' promoter (0.61 kbp; origin: *Agrobacterium tumefaciens* pTi15955) and shares the ORF25PolyA terminator. The function of the PAT protein in 281-24-236/3006-210-23 cotton is to confer tolerance against glufosinate-ammonium during the genetic modification.

## INFORMATION RELATING TO THE GMHP

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

281-24-236/3006-210-23 cotton plants express Cry1F, Cry1Ac and PAT proteins conferring resistance to certain lepidopteran insect pests under field conditions.

The *cry1F* and *cry1Ac* genes are expressed constitutively by the (4ocs)DeltaMas 2'- and *ubiZM1(2)*- promoter respectively. Expression of Cry1F and Cry1Ac proteins provides control against lepidopteran insect pest damage to the above-ground parts of the cotton plant including those parts which are beyond the reach of chemical insecticides. Specifically, the Cry1F and Cry1Ac proteins confer season-long resistance against cotton bollworm (*Helicoverpa zea*) pink bollworm (*Pectinophora gossypiella*) and tobacco budworm (*Heliothis virescens*). They also confer good control against several armyworm- and two different looper- species.

The *pat* gene is also expressed constitutively conferring tolerance against glufosinate-ammonium during the genetic modification.

No other new traits have been introduced into 281-24-236/3006-210-23 cotton, in particular antibiotic resistance markers. This is confirmed by the molecular characterization (**Point 30(f)** of this notification), protein expression analysis (**Point 38** of this notification), the expected agronomic performance (**Point 42** of this notification), and comparable composition data to other conventional cotton (**Annex 1** to notification).

## **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 analysis using genomic DNA of 281-24-236/3006-210-23 cotton were used to demonstrate the integration, copy number, and integrity of *cry1Ac*, *cry1F* and *pat* genes as well as to prove the absence of the erythromycin resistance gene, *ery<sup>R</sup>*, in the stacked transgenic cotton line. Results of this study show that this stack 281-24-236/3006-210-23 cotton contains identical Southern blot patterns as previously determined for the parental transgenic lines.



**(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, mitochondrion, or maintained in a non-integrated form), and methods for its determination**

The inserts are integrated into the cotton plant genome as confirmed in the molecular characterisation of 281-24-236/3006-210-23 cotton by detailed Southern blot analysis and DNA sequencing.

**(d) Copy number and genetic stability of the insert**

The actual insert in 281-24-236/3006-210-23 cotton contains a single integration of transgenic DNA from *cry1F* and *cry1Ac* transgenes. The insert from *cry1F* event 281-24-236 contains one intact copy of the insect resistance gene *cry1F*, and one intact copy plus an additional hybridising fragment of the plant selectable marker gene *pat*. The insert from *Cry1Ac* event 3006-210-23 contains one intact copy of the insect resistance gene *cry1Ac*, and one intact copy of the plant selectable marker gene *pat*. The data also confirm that the gene *ery<sup>R</sup>* conferring resistance to erythromycin is not present in the stacked cotton 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 expression of Cry1F, Cry1Ac and PAT proteins were evaluated in several tissue samples of 281-24-236/3006-210-23 cotton and corresponding parental lines 281-24-236 and 3006-210-23, collected from six field locations in the US during 2001. Tissue samples of cottonseed, pollen, nectar, and cottonseed-processed samples: meal and oil were analysed using ELISA methods at a limit of detection ranging from 0.001 – 0.4 ng protein/mg sample weight.

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

Average expression levels of Cry1F across matrixes, ranges from not detected up to 25.3 ng/mg sample weight. Moreover, the level of Cry1F protein detected in pollen was 0.06 ng/mg and below the limit of detection on nectar.

Average level of expression of Cry1Ac protein ranges from non detectable up to 1.83 ng/mg. Furthermore, expression level of Cry1Ac protein on pollen was on average 1.45 ng/mg and not detectable in nectar.

PAT protein was expressed across several matrixes at an average expression level ranging from non detectable up to 0.54 ng/mg. Expression level of PAT protein in pollen was on average 0.05 ng/mg while in nectar was undetectable.

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

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

Comparisons between 24-236/3006-210-23 cotton and non-transgenic recurrent parent were made on: growth habit, field emergence, vegetative- and flowering- vigour and reproductive potential.

Data collected from field trials conducted during 2001 demonstrated no significant morphological-, growth- or developmental- differences between 281-24-236/3006-210-23 cotton and conventional varieties.

### **(b) Dissemination**

The 281-24-236/3006-210-23 cotton plants show no difference in dissemination compared to non-GM cotton. Commercial cotton varieties have been domesticated to the extent that it cannot be disseminated without human intervention.

### **(c) Survivability**

Cultivated cotton varieties have been domesticated to the extent that they can not survive outside managed agricultural environments. Lack of weediness traits prevents cottonseeds to readily survive from one growing season to the next. The genetic modification in 281-24-236/3006-210-23 cotton results in expression of Cry1F, Cry1Ac and PAT proteins conferring resistance to certain lepidopteran insect pests and expression under field conditions. The survival characteristics of 281-24-236/3006-210-23 cotton in the environment remain comparable to those of non-GM cotton.

**(d) Other differences**

Cotton does not exhibit any weedy tendencies and is non-invasive in natural ecosystems. Based on the agronomic data, there is no evidence for altered survival, multiplication, or dissemination of 281-24-236/3006-210-23 cotton in the environment as compared to non-GM cotton. In addition, the inserted traits do not alter the phenotype of cotton in a way that would confer a fitness advantage for cotton outside managed agricultural environments.

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

The potential for gene transfer to sexually compatible plant species will be negligible because this notification is for the import of 281-24-236/3006-210-23 cotton and not for cultivation. Therefore, any release of 281-24-236/3006-210-23 cotton into the environment will be unintentional, limited and highly unlikely to have any adverse effect. If necessary, such limited release can be easily controlled by the application of current management practices used for the control of unintentional releases of cotton plants, such as the application of non-selective herbicides with the exception of glufosinate-ammonium. In any case, there are no sexually compatible wild or weedy relatives of *Gossypium hirsutum* known to exist in the EU, which eliminates the possibility of potential gene transfer to such species.

Transfer of transgenes originating from 281-24-236/3006-210-23 cotton to bacteria is a negligible concern. There is no known mechanism for, or definitive demonstration of, DNA transfer from plants to microbes under natural conditions. Even if horizontal gene transfer were to take place, transfer of the *cry1F*, *cry1Ac* or *pat* gene from 281-24-236/3006-210-23 cotton does not represent a risk to human or animal health nor is it of consequence as a plant

pest risk. The *ery*<sup>R</sup> gene coding for resistance to the antibiotic erythromycin is not present in 281-24-236/3006-210-23 cotton.

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

### (i) Toxicity

The genetic modification in 281-24-236/3006-210-23 cotton results in expression of Cry1F, Cry1Ac and PAT proteins. The Cry1F and Cry1Ac proteins have specific toxicity against certain lepidopteran insect pests (target organisms). An acute toxicity study with a 50:50 mixture of Cry1F and Cry1 AC proteins in mice has confirmed the safety of the Cry1F and Cry1Ac proteins to human and animal health.

No mortality, toxicity or adverse clinical signs were observed at the highest dose tested of 375 mg and 350 mg of Cry1F and Cry1Ac pure proteins/kg of body weight. In addition, there is no evidence for CRY proteins originating from *Bacillus thuringiensis* to have harmful effects on the health of humans and animals.

The safety in terms of toxicity for the PAT protein has already been analysed. The *pat* gene was originally obtained from *Streptomyces viridochromogenes* strain Tü494 which has no known toxic or pathogenic potential. In 1997, EPA issued a final rule exempting PAT from the requirement of a tolerance in all raw agricultural commodities when used as “plant incorporated protectants” (PIP) (FR April the 11, 1997, vol. 62, N°70). In exempting PAT, EPA evaluated data submitted regarding its behaviour in simulated digestive fluid and the acute oral toxicity of the protein. PAT protein didn’t show mortality in the high-dose 2500 mg/kg subgroup test of animals and *in vitro* digestibility data indicated that PAT is degraded rapidly.

In addition, a poultry feeding study over a period of 42 days has been carried out confirming that there are no statistically significant differences on mortality, body weight gain or feed conversion between chickens fed a diet containing seeds from 281-24-236/3006-210-23 cotton or from non-GM cotton.

#### (ii) Allergenicity

The most important factor to consider in assessing allergenic potential is whether the source of the gene being introduced into plants is known to be allergenic. Neither *Bacillus thuringiensis* (the source of the *cry1F* and *cry1Ac* genes) nor *Streptomyces viridochromogenes* (the source of the *pat* gene) have a history of causing allergy. Also, both donor organisms are common soil bacteria.

The assessment of the allergenic potential of the Cry1F, Cry1Ac and PAT proteins has been made following the recommendations and the application of the decision-tree from FAO/WHO. The analyses have consisted of amino acid sequence comparison with known allergens, rapid degradation in simulated gastric fluids, relatively low level of expression, lack of glycosylation and thermolability. The results confirm that Cry1F, Cry1Ac and PAT proteins do not pose any significant risk of being a potential allergen.

(iii) Ecotoxicity studies

The absence of toxicity of the Cry1F and Cry1Ac proteins to non-target and beneficial organisms has been thoroughly assessed in multiple dietary toxicity studies including green lacewing larvae, ladybird beetle, beneficial parasitic Hymenoptera *Nasonia vitripennis*, Monarch butterfly larvae, honey bees, earthworm, collembola and daphnia.

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

Same as above

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

This notification is for the import of 281-24-236/3006-210-23 cotton and does not include cultivation in the EU. Therefore, there is no likelihood of any significant interaction between 281-24-236/3006-210-23 cotton plants and target organisms.

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

This notification is for the import of 281-24-236/3006-210-23 cotton and does not include cultivation in the EU. Therefore, there is no likelihood of any significant interaction between 281-24-236/3006-210-23 cotton plants and non-target organisms.

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

Plant parts of 281-24-236/3006-210-23 cotton can be analysed by ELISA to detect the proteins expressed by the *cry1F*, *cry1Ac* and *pat* genes. Additionally, an insect bioassay with sensitive lepidopteran insect species such as cotton bollworm (*Helicoverpa zea*) pink bollworm (*Pectinophora gossypiella*) can be used to identify cotton plants expressing the Cry1F and Cry1Ac proteins.

A PCR detection method to confirm the molecular identity of 281-24-236/3006-210-23 cotton has been developed. The PCR method can also be used to confirm presence of 281-24-236/3006-210-23 cotton for the purposes of labelling products containing or derived from 281-24-236/3006-210-23 cotton. The detection method and seed of 281-24-236/3006-210-23 cotton as reference material is provided to the Dutch regulatory authority. The PCR detection method and reference material will also be available to a central body operating under the auspices of the EU regulatory authorities and the European Commission.

A combination of the techniques described above can be used to identify 281-24-236/3006-210-23 cotton.



## 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 GMO(s) (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)**

This notification is to import 281-24-236/3006-210-23 cottonseeds and products derived from. Cottonseeds and other products derived from 281-24-236/3006-210-23 cotton will be imported, stored and processed for use in food, animal feed and industrial products in the same way as other conventional cotton. This notification does not include the cultivation of 281-24-236/3006-210-23 cotton in the EU and therefore the environmental impact from import of 281-24-236/3006-210-23 cotton will be negligible as summarised in the environmental risk assessment (e.r.a.) (**Section 3**).

As intended by the genetic modification in 281-24-236/3006-210-23 cotton, specific advantages for the agricultural environment have been conferred to 281-24-236/3006-210-23 cotton: resistance to certain lepidopteran pests, such as cotton bollworm, pink bollworm and tobacco budworm under field conditions. However, commercial cotton varieties are highly domesticated, to the extent that they cannot become established as a feral species outside the agricultural environment, and the specific advantages introduced in 281-24-236/3006-210-23 cotton do not confer any selective advantage to the cotton plants in the natural environment, i.e. outside the agricultural environment. In addition, the scope of this notification for import of 281-24-236/3006-210-23 cotton excludes cultivation, and the e.r.a. (**Section 3**) has determined that any risks to human and animal health or the environment from the placing on the market (import) of 281-24-236/3006-210-23 cotton is as negligible as for any conventional cotton.

**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)**

This notification is to import 281-24-236/3006-210-23 cottonseed and corresponding by-products, and does not include cultivation in the EU. Therefore, there will be no significant direct and/or indirect interactions of 281-24-236/3006-210-23 cotton with target organisms.

**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**

**(b) Effects on biodiversity in other habitats**

**(c) Effects on pollinators**

**(d) Effects on endangered species**

This notification is for the import of 281-24-236/3006-210-23 cotton and does not include cultivation in the EU. Therefore, there will be no environmental impact resulting from potential interactions of 281-24-236/3006-210-23 cotton with non-target organisms.

**C. INFORMATION RELATING 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**

None

**(b) Conclusions of post-release monitoring**

**(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)**

**(a) Notification number**

None

**(b) Conclusions of post-release monitoring**

**(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)**

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

**(a) Release country**

U.S.A.

**(b) Authority overseeing the release**

USDA and EPA.

**(c) Release site**

Multiple sites.

**(d) Aim of the release**

Research.

**(e) Duration of the release**

Three seasons.

**(f) Aim of post-release monitoring**

Control of potential volunteers.

**(g) Duration of post-release monitoring**

One season.

**(h) Conclusions of post-release monitoring**

281-24-236/3006-210-23 cotton plants performed as expected, with no evidence of any unintentional morphological or phenotypical characteristics. In particular, there was no evidence of enhanced weediness of 281-24-236/3006-210-23 cotton.

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

No adverse effects on human health and the environment observed.

**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 (e.r.a.) (**Section 3**) concluded that the introduced traits, characteristics and interaction with the environment of imported 281-24-236/3006-210-23 cotton will not give rise to any identified adverse effect to human and animal health or the environment. Therefore, the risk to human and animal health or the environment arising from the placing on the market (import) of 281-24-236/3006-210-23 cotton is as negligible as for any conventional cotton, concluding that 281-24-236/3006-210-23 cotton is as safe as any commercially available cotton regarding human and animal health or the environment.

Case-specific monitoring should only be carried out in those cases where potential adverse effects have been identified in the e.r.a. Due to the absence of identified adverse effects in the e.r.a., case-specific monitoring is not applicable to the placing on the market (import) of 281-24-236/3006-210-23 cotton.

As detailed in the e.r.a., any exposure to the environment from the import of 281-24-236/3006-210-23 cotton will be limited to any unintended release of 281-24-236/3006-210-23 cotton e.g. via spillage during transportation of the seed. However, this limited exposure will not give rise to any adverse environmental impact, and if necessary, can be easily controlled by the application of current agricultural practices used for the control of volunteer cotton plants, such as tilling or the application of non-selective herbicides with the exception of glufosinate-ammonium.

Therefore, application of established routine surveillance practices (e.g. the monitoring of agricultural cultivars or plant protection products) for the general surveillance of the occurrence of unanticipated adverse effects to conventional agricultural practice due to the placing on the market of 281-24-236/3006-210-23 cotton as imports is not necessary.

However and since the majority of imported cottonseed is used for animal feed purposes, general surveillance might assist in confirming the safety to the environment, arisen from involuntary spillage into the environment of 281-24-236/3006-210-23 cottonseeds, in surrounding areas of port of entry into the EU and where cottonseeds are processed into animal feed products, with a view to safeguarding against any unanticipated effects. If this is considered necessary, we can discuss with the relevant national Competent Authorities and associated bodies the co-ordination of a surveillance network, where appropriate, within the framework of their routine surveillance.