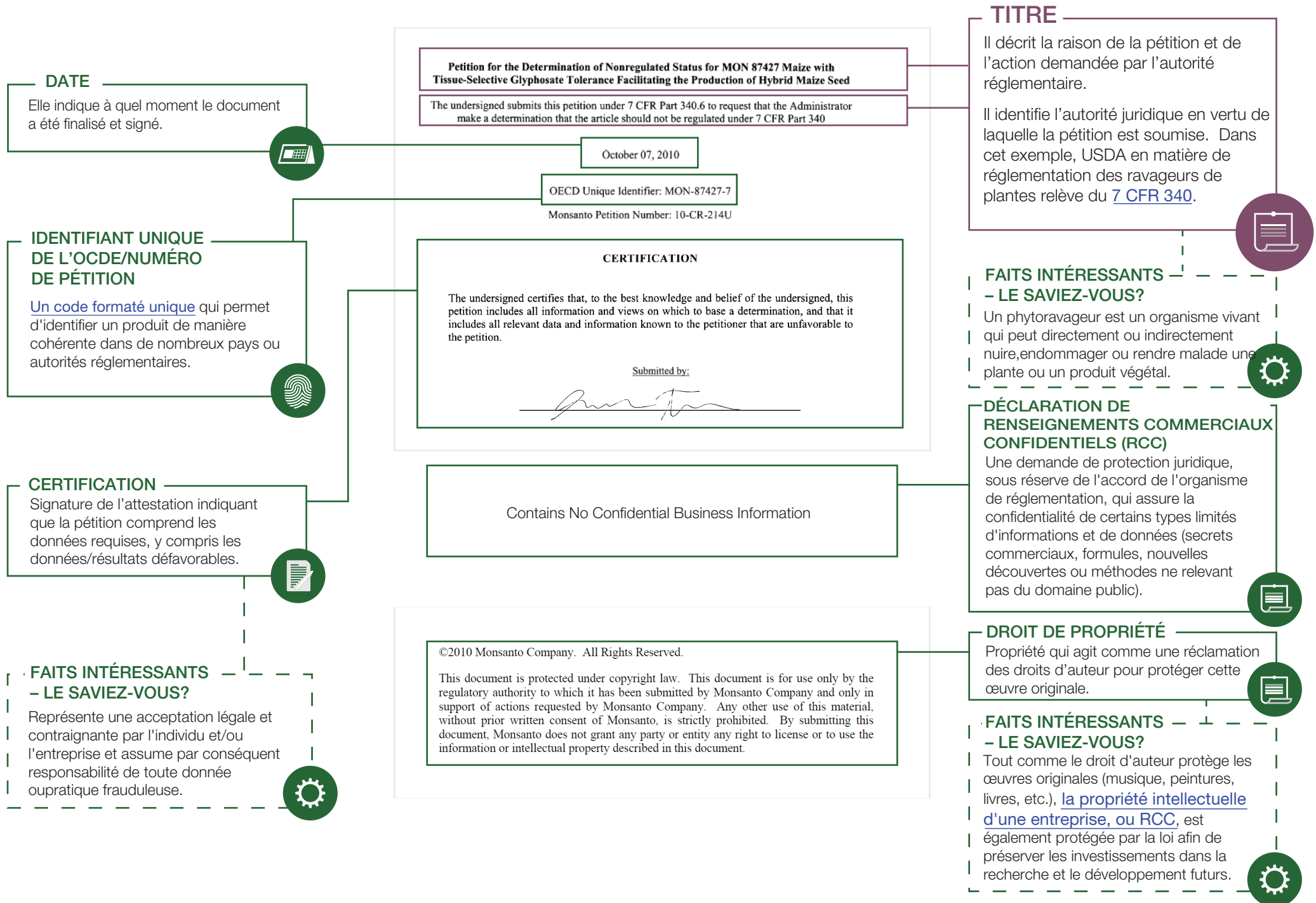


Comment lire un document de soumission des cultures GM américain

Les documents de soumission peuvent être assez longs et pas toujours faciles à comprendre. Pour vous aider à lire et à comprendre, ce guide vous expliquera en détail les parties et les sections les plus importantes d'un document USDA, et mettra l'accent sur l'index des études de l'EPA.





RÉSUMÉ EXÉCUTIF

Brève description des informations, données et conclusions que contiendra la pétition complète.



EXECUTIVE SUMMARY

Monsanto Company has developed biotechnology-derived MON 87427 maize with tissue-selective glyphosate tolerance to facilitate the production of viable hybrid maize seed. MON 87427 produces the same 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein that is produced in commercial Roundup Ready® crop products, via the incorporation of a *cp4 epsps* coding sequence.

The data and information presented in this petition demonstrate MON 87427 is agronomically, phenotypically, and compositionally comparable to conventional maize with the exception of the introduced trait. Moreover, the data presented demonstrate MON 87427 is unlikely to pose an increased plant pest risk, including weediness or adverse environmental impact, compared to conventional maize.

Based on the data and information presented in this petition, it is concluded that MON 87427 is not likely to be a plant pest. Therefore, Monsanto Company requests a determination from APHIS that MON 87427 and any progeny derived from crosses between MON 87427 and conventional maize or deregulated biotechnology-derived maize be granted nonregulated status under 7 CFR Part 340.

JUSTIFICATION

Récit expliquant le fondement du produit, ses avantages et son utilité. Il décrit également la base juridique de l'action de l'agence (la décision de/ne pas déréglementer). De plus, cette section décrit le cadre coordonné entre les agences américaines, pour s'assurer que nous respectons toutes les réglementations nécessaires des autres agences qui peuvent être requises pour les aliments (FDA) et l'environnement (EPA).



I.B. Rationale for the Development of MON 87427 Maize with Tissue-Selective Glyphosate Tolerance

Monsanto Company is submitting this request to APHIS for a determination of nonregulated status in whole for the new biotechnology-derived maize product, MON 87427, any progeny derived from crosses between MON 87427 and conventional maize, and any progeny derived from crosses of MON 87427 with other biotechnology derived maize that has been granted nonregulated status under 7 CFR § 340.

Maize hybrids have been, and still are, developed and used based on the positive yield increases and plant vigor associated with heterosis, which is also known as hybrid vigor (Duvick, 2001). Inherent to the cultivation of hybrid plants, seed produced from hybrid plants is typically not used for replanting, due to the loss of hybrid vigor.

Under the Coordinated Framework for Regulation of Biotechnology, the responsibility for regulatory oversight of biotechnology-derived crops falls primarily on three federal agencies: EPA, FDA and USDA (USDA, 1986). Deregulation of MON 87427 by USDA constitutes only one component of the overall regulatory oversight and review of this product. As a practical matter, MON 87427 cannot be released and marketed until FDA and USDA have completed their reviews and assessments under their respective jurisdictions.

FAITS INTÉRESSANTS – LE SAVIEZ-VOUS?

En vertu de la Loi sur la protection des végétaux, l'USDA-APHIS exerce une surveillance réglementaire sur les produits de la biotechnologie moderne qui pourraient présenter un risque phytosanitaire. Depuis 1986, l'importation, la manipulation, les mouvements interétatiques et la libération dans l'environnement d'organismes réglementés sont réglementés.



Zea mays subspecies *mays* (*L.*), referred to as maize in this petition, is a versatile crop that provides food, feed, and fuel to the global economy. The biology of maize is well understood and documented. The Organization for Economic Co-operation and Development (OECD) Consensus Document on the Biology of *Zea mays* subsp. *mays* (Maize) (OECD, 2003) provides key information on:

- i. general description of maize biology, including taxonomy, morphology, and the use of maize as a crop plant
- ii. agronomic practices in maize cultivation
- iii. geographic centers of origin
- iv. reproductive biology
- v. cultivated maize as a volunteer weed
- vi. inter-species/genus introgression into relatives and interactions with other organisms
- vii. summary of the ecology of maize

MON 87427 was developed through *Agrobacterium*-mediated transformation of maize immature embryos from line LH198 × HiII utilizing PV-ZMAP1043. This section describes the plasmid vector, the donor gene, and the regulatory elements used in the development of MON 87427 as well as the deduced amino acid sequence of the CP4 EPSPS protein produced in MON 87427. In this section, transfer DNA (T-DNA) refers to DNA that is transferred to the plant during transformation. An expression cassette is comprised of sequences to be transcribed and the regulatory elements necessary for the expression of those sequences.

Characterization of the DNA insert in MON 87427 was conducted by Southern blot analyses, PCR and DNA sequencing. The results of this characterization demonstrated that MON 87427 contains a single copy of the *cp4 epsps* expression cassette, also referred to in this petition as transfer DNA (T-DNA), that is stably integrated at a single locus and is inherited according to Mendelian principles over multiple generations. These conclusions were based on several lines of evidence: 1) Southern blot analyses assayed the entire maize genome for the presence of DNA derived from PV-ZMAP1043, and demonstrated that only a single copy of the T-DNA was inserted at a single site and no plasmid vector backbone sequences were detected in MON 87427; 2) DNA sequencing analyses determined the exact sequence of the inserted DNA and allowed a comparison to the T-DNA sequence in the plasmid vector confirming that only the expected sequences were integrated; 3) Southern blot fingerprint analyses demonstrated the stability of the T-DNA present in MON 87427 over five generations; and 4) segregation analyses showed expected heritability and stability of the insert occurred across multiple generations. Taken together, the characterization of the genetic modification demonstrates that a single copy of the T-DNA was stably integrated at a single locus of the genome.

BIOLOGIE DE LA PLANTE

Évaluation du caractère de nuisibilité par rapport à son homologue conventionnel. Elle jette les bases des évaluations comparatives de ce que nous savons déjà d'une plante acceptable aujourd'hui pour s'assurer que l'espèce végétale GM n'est pas différente de celle qui est actuellement cultivée.



DESCRIPTION DE LA MODIFICATION GÉNÉTIQUE

Description de la manière dont le matériel génétique (ADN) a été introduit dans la plante hôte. Elle répond à la question : « Qu'avions-nous l'intention de faire ? »



CARACTÉRISATION DE LA MODIFICATION GÉNÉTIQUE

Informations détaillées sur l'ADN introduit et la stabilité (identique au fil du temps) du matériel génétique introduit. Elle répond à la question : « Qu'avions-nous réellement fait? »



FAITS INTÉRESSANTS

– LE SAVIEZ-VOUS?

Les tests de stabilité sont importants pour s'assurer que, lorsque le caractère est reproduit de manière conventionnelle dans d'autres contextes génétiques, il présente toujours la ou les mêmes caractéristiques.



DONNÉES BRUTES

Les données brutes sont des données originales telles qu'elles ont été recueillies pendant l'étude, avant de les résumer pour analyse. Elles sont comprises dans les soumissions au niveau des sections pertinentes traitant des résultats.

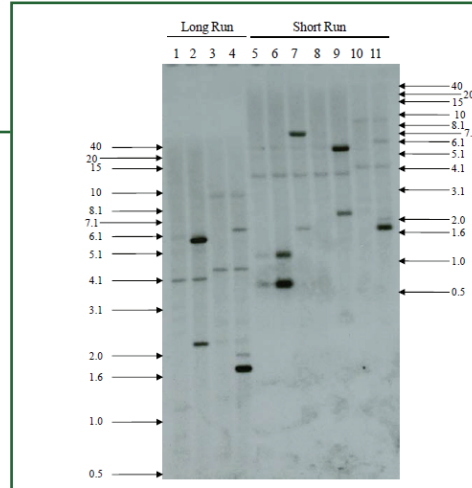


Figure IV-2. Southern Blot Analysis to Determine Insert and Copy Number of the T-DNA in MON 87427: Probe 1 and Probe 4

The blot was hybridized with two 32 P-labeled probes that spanned portions of the T-DNA sequence (Figure III-1, Probe 1 and Probe 4). Each lane contains ~10 μ g of digested genomic DNA isolated from maize seed. Lane designations are as follows:

Lane	Description
1	Conventional control (<i>Nco</i> I)
2	MON 87427 (<i>Nco</i> I)
3	Conventional control (<i>Nsi</i> I)
4	MON 87427 (<i>Nsi</i> I)
5	Conventional control (<i>Nco</i> I) spiked with Probe 1 and Probe 4 [-0.1 genome equivalent]
6	Conventional control (<i>Nco</i> I) spiked with Probe 1 and Probe 4 [-1.0 genome equivalent]
7	Conventional control (<i>Nco</i> I) spiked with PV-ZMAP1043 (<i>Sph</i> I) [-1.0 genome equivalent]
8	Conventional control (<i>Nco</i> I)
9	MON 87427 (<i>Nco</i> I)
10	Conventional control (<i>Nsi</i> I)
11	MON 87427 (<i>Nsi</i> I)

Arrows denote the size of the DNA, in kilobase pairs, obtained from the 1 Kb DNA Extension Ladder (Invitrogen) on the ethidium bromide stained gel.

CARACTÉRISATION ET ÉVALUATION DE LA SÉCURITÉ DES PROTÉINES PRODUITES

Les analyses de la protéine ou des protéines (pour évaluer l'adéquation à la consommation humaine) et animale et le risque phytosanitaire.

Certains éléments de la protéine étudiés comprennent:

- // l'historique de la consommation sûre
- // les propriétés physiques et fonctionnelles
- // les quantités dans plusieurs tissus végétaux
- // la similitude avec les toxines/allergènes protéiques connus
- // la digestibilité simulée des mammifères
- // les évaluations de toxicité à haute dose chez les mammifères



Characterization of the introduced protein in a biotechnology-derived crop is important to establishing food, feed, and environmental safety. As described in Section IV, MON 87427 contains a *cp4 epsps* expression cassette that, when transcribed and translated, results in the expression of the CP4 EPSPS protein.

This section summarizes: 1) the identity and function of the CP4 EPSPS protein produced in MON 87427; 2) demonstration of the equivalence of the plant-produced and *E. coli*-produced proteins; 3) the level of the CP4 EPSPS protein in MON 87427 plant tissues; 4) assessment of the potential allergenicity of the CP4 EPSPS protein produced in MON 87427; and 5) the food, feed, and environmental safety assessment of the CP4 EPSPS protein produced in MON 87427. The data support a conclusion that MON 87427 is safe for the environment and human or animal consumption based on several lines of evidence summarized below.

- FAITS INTÉRESSANTS -

- LE SAVIEZ-VOUS?

- | L'ADN dirige la production d'une ou de plusieurs protéines qui confèrent à une plante un caractère spécifique ou particulier (trait) comme la tolérance aux herbicides, la protection contre certains insectes.

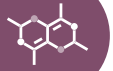


Safety assessments of biotechnology-derived crops typically include comparisons of the composition of forage and grain of the GE crop to that of conventional counterparts (Codex Alimentarius, 2003). Compositional assessments were performed using the principles and analytes outlined in the OECD consensus document for maize composition (OECD, 2002).

A recent review of compositional assessments conducted according to OECD guidelines that encompassed a total of seven GE crops, nine countries and 11 growing seasons concluded that incorporation of biotechnology-derived agronomic traits has had little impact on natural variation in crop composition; most compositional variation is attributable to growing region, agronomic practices, and genetic background (Harrigan, et al., 2010). Compositional quality therefore implies a very broad range of endogenous levels of individual constituents. Numerous scientific publications have further documented the extensive variability in the concentrations of crop nutrients, anti-nutrients, and secondary metabolites that reflects the influence of environmental and genetic factors as well as extensive conventional breeding efforts to improve nutrition, agronomics, and yield (Harrigan, et al., 2007; OECD, 2002; Reynolds, et al., 2005; Ridley, et al., 2004).

ÉVALUATION DE LA COMPOSITION DU CARACTÈRE

Analyses des principaux nutriments et anti-nutriments (ceux qui diminuent l'utilité des nutriments/valeur nutritive) dans les parties de la plante consommées par les êtres humains et les animaux par rapport aux niveaux d'une plante conventionnelle cultivée et récoltée dans des conditions similaires.



- FAITS INTÉRESSANTS - - LE SAVIEZ-VOUS?

Ces évaluations identifient les éventuels effets indésirables dus à l'introduction de l'ADN ou à la production de la protéine introduite dans le métabolisme de la plante.



This section provides an evaluation of the phenotypic and agronomic characteristics and the environmental interactions of MON 87427 compared to the conventional control (LH198 × LH287). The data support a determination that MON 87427 is similar to conventional maize with the exception of the tissue-selective glyphosate tolerance and, therefore, is no more likely to pose a plant pest risk or to have a significant environmental impact than conventional maize. The conclusions are based on the results of the multiple evaluations reported herein.

Phenotypic, agronomic, and environmental interaction characteristics of MON 87427 were evaluated in a comparative manner to assess plant pest potential (OECD, 1993). These assessments included evaluation of five seed germination parameters, 14 plant growth and development characteristics, observations for plant responses to abiotic stress, plant-disease and plant-arthropod interactions, and two pollen characteristics. Results from the phenotypic, agronomic, and environmental interaction assessments indicate that MON 87427 does not possess weedy characteristics, increased susceptibility or tolerance to specific abiotic stresses, diseases, or arthropods, or characteristics that would confer a plant pest risk or a significant environmental impact compared to conventional maize.

ÉVALUATION PHÉNOTYPIQUE, AGRONOMIQUE ET INTERACTIONS ENVIRONNEMENTALES

Évaluation comparative de l'observation visuelle de la croissance et du développement de la plante. Des analyses supplémentaires sont menées pour évaluer la manière dont la plante interagit avec son environnement physique et les organismes biologiques à travers une combinaison d'évaluations sur le terrain et en laboratoire.



TABLEAU

Les tableaux présentent efficacement un résumé des données dans un format numérique ou statistique par rapport à un texte de contenu identique.



Table VII-4. Plant Growth and Development across 16 Locations during 2008

Phenotypic Characteristic (units)	Mean (S.E.)		Reference Range ¹	
	MON 87427	Control	Min	Max
Seedling vigor (1-9 scale)	2.7 (0.19)*	2.4 (0.17)	1.0	5.0
Early stand count ² (#/plot)	67.7 (1.69)	70.3 (2.01)	55.7	80.3
Days to 50% pollen shed	63.9 (1.15)	63.5 (1.19)	45.7	78.0
Days to 50% silking	62.9 (1.07)	62.7 (1.09)	46.7	75.0
Stay green ³ (1-9 scale)	5.9 (0.34)	5.6 (0.35)	2.0	9.0
Ear height (in)	42.0 (0.89)	41.9 (0.97)	26.3	56.1
Plant height ⁴ (in)	91.4 (1.50)	90.8 (1.50)	73.9	103.1
Dropped ears ⁵ (#/plot)	0.6 (0.22)	0.5 (0.17)	0.0	2.7
Stalk lodged plants ⁵ (#/plot)	7.7 (2.58)	5.5 (1.77)	0.0	71.3
Root lodged plants (#/plot)	7.5 (2.49)	5.3 (2.08)	0.0	25.9
Final stand count ⁶ (#/plot)	60.8 (0.89)	60.4 (0.88)	54.7	65.8
Grain moisture ⁶ (%)	19.6 (0.55)	20.3 (0.62)	16.0	27.4
Test Weight ⁶ (lbs/bu)	55.3 (0.33)	55.2 (0.38)	51.6	58.6
Yield ⁶ (bu/a)	156.9 (5.47)	165.4 (6.71)	94.6	193.8

Note: the experimental design was a randomized complete block design with three replications at each site. S.E. = standard error. N = 48 except where noted.

* Indicates statistically significant difference between MON 87427 and the conventional control ($\alpha=0.05$).

¹Reference range was calculated from the minimum and maximum mean values from among the 38 unique reference hybrids.

PRATIQUES AGRONOMIQUES AUX ÉTATS-UNIS

Évaluation pour déterminer si les nouvelles caractéristiques de la plante changeront le mode de culture des producteurs ; elle comprend également une description des pratiques de gestion que les producteurs peuvent mettre en œuvre pour une utilisation durable de ce caractère introduit.



The U.S. Code of Federal Regulations, 7 CFR § 340.6(c)(4), requires that potential impacts to agricultural and cultivation practices be considered as part of plant pest risk assessments. This section is a summary of current agronomic practices in the U.S. for producing hybrid maize seed and, to a lesser extent, grain production. The innovation realized by MON 87427 will occur only on acres used for the production of hybrid maize seed. This section is included in this petition as a baseline to assess possible impacts to agricultural practices due to the introduction of MON 87427.

Hybridization is a fundamental concept used in maize breeding and production programs in the U.S. and most of the world. The fixation of alleles in pure lines (i.e., inbreds) causes a general reduction in maize vigor and productivity, but hybridization can improve vigor in the maize that is grown from the F1 hybrid seed² produced through crossing two inbred lines. Modern maize breeding is based on selecting inbred lines and producing crosses that possess desirable traits. Recent techniques such as marker-assisted selection can also reduce the time and cost required to achieve breeding goals (Yousef and Juvik, 2001). MON 87427 maize with tissue-selective glyphosate tolerance was developed to facilitate the production of viable hybrid maize seed. Use of MON 87427 and specifically timed glyphosate applications eliminates or greatly reduces the need for the manual and mechanical detasseling currently used in hybrid maize seed production.

This section provides a brief review and assessment of the plant pest potential of MON 87427 and its impact on agronomic practices as well as the environmental impact of the introduced CP4 EPSPS protein. USDA-APHIS has responsibility, under the Plant Protection Act (PPA) (7 U.S.C. § 7701-7772), to prevent the introduction and dissemination of plant pests into the U.S. Regulation 7 CFR § 340.6 provides that an applicant may petition APHIS to evaluate submitted data to determine that a particular regulated article does not present a plant pest risk and should no longer be regulated. If APHIS determines that the regulated article does not present a plant pest risk, the petition is granted, thereby allowing unrestricted introduction of the article.

According to the PPA, the definition of "plant pest" includes living organisms that can directly or indirectly injure, damage, or cause disease in any plant or plant product (7 U.S.C. § 7702[14]). The regulatory endpoint under the PPA for biotechnology-derived crop products is not zero risk, but rather a determination that deregulation of the article in question is not likely to pose a plant pest risk. Information in this petition related to plant pest risk characteristics includes; mode of action and changes to plant metabolism, composition, expression and characteristics of the gene product, potential for weediness of the regulated article, impacts to NTO, disease and pest susceptibilities, impacts on agronomic practices, impacts on the weediness of any other plant with which it can interbreed, as well as the potential for gene flow.

Monsanto knows of no study results or observations associated with MON 87427 or the CP4 EPSPS protein indicating that there would be an adverse environmental consequence from the introduction of MON 87427. MON 87427 produces the CP4 EPSPS protein in the vegetative and female reproductive tissues, rendering the leaf, stalk and root tissues and the tissues that develop into seed or grain in the maize plant tolerant to the herbicide glyphosate. However, limited to no CP4 EPSPS protein is expressed in the tapetum and pollen microspore cells in MON 87427, thus these tissues and pollen are not tolerant to the herbicide glyphosate. The CP4 EPSPS protein produced in MON 87427 is identical to the CP4 EPSPS protein present in Roundup Ready crop products that were previously granted a determination of nonregulated status by APHIS, and has been widely planted in the U.S. and globally. As demonstrated by field results and laboratory tests, the only phenotypic difference between MON 87427 and conventional maize is glyphosate tolerance during vegetative and female reproductive stages.

The data and information presented in this petition demonstrate that MON 87427 is unlikely to pose an increased plant pest risk or to have an adverse environmental consequence compared to conventional maize. This conclusion is reached based on multiple lines of evidence developed from a detailed characterization of the product compared to conventional maize, followed by risk assessment on detected differences.

ÉVALUATION PHYTOSANITAIRE

Conclusion rassemblant tous les éléments des analyses et évaluations précédentes pour déterminer si l'espèce végétale GM présentera ou non un risque phytosanitaire accru.



– FAITS INTÉRESSANTS –

– LE SAVIEZ-VOUS?

Dans son évaluation des espèces végétales GM, l'USDA tient compte de éléments suivants :

- // l'impact du matériel génétique inséré sur le potentiel phytosanitaire ainsi que sur la susceptibilité aux maladies et aux parasites
- // les impacts potentiels sur les organismes non ciblés bénéfiques pour l'agriculture
- // la possibilité d'enherbement amélioré de la plante GM
- // l'impact potentiel sur l'enherbement d'autres plantes avec lesquelles la plante génétiquement modifiée peut se croiser
- // les changements potentiels dans l'agriculture ou les pratiques culturales



CONSÉQUENCES NÉGATIVES DE L'INTRODUCTION

Déclaration que nous ne connaissons aucune information supplémentaire non déjà décrite qui pourrait indiquer les conséquences néfastes de la libération générale de la nouvelle plante.



RÉFÉRENCES

À la fin de chaque soumission, une liste de toutes les références évoquées est fournie, notamment les articles scientifiques, les directives et protocoles utilisés et les réglementations.



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Al-Kaisi, M., M.H. Hanna and M. Tidman. 2003. Crop rotation considerations for 2004 management season rotation. Iowa State University, Ames, Iowa. <http://www.ipm.iastate.edu/ipm/icm/2003/12-15-2003/croprotation.html> [Accessed June 19, 2006].



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

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DATA MATRIX

Date August 16, 2002	EPA Reg No./File Symbol: 524-522	Page 1 of 7
Applicant's/Registrant's Name & Address Monsanto Company, 600 13th Street N.W., Suite 660, Washington, D.C. 20005		Product: Bollgard® II Cotton
Ingredient A <i>Bacillus thuringiensis</i> Cry2Ab2 protein and the genetic material necessary for its production in Bollgard® II cotton event 15985		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials in Support of the Request for the Exemption from the Requirement of Tolerance for Glucuronidase (GUS) as a Plant-Incorporated Protectant Formulation Inert Ingredient.	44939407	Monsanto Company	OWN	
	Administrative Materials in Support of the Amendment for the Request for Exemption from the Requirement of Tolerance for Cry2Ab (Petition PP 7F4888).	44966600	Monsanto Company	OWN	
	Validated Method for Detection and Direct ELISA Analysis of Cry2Ab2 in Cottonseed An unpublished study conducted by Monsanto Company	Not yet assigned	Monsanto Company	OWN	Submitted 13-Apr-01
	Insect Resistance Management Plan for Bollgard II Cotton An unpublished study conducted by Monsanto Company	45545701	Monsanto Company	OWN	
	Public Interest Document Supporting the Registration of the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab Insect Control Protein, as Produced in Cotton (<i>Gossypium hirsutum</i> L.)	Not yet assigned	Monsanto Company	OWN	Submitted 11-Dec-01
	Administrative Materials in Support of the Request for the Registration of the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab Insect Control Protein, as Produced in Corn (<i>Zea mays</i> L.) and Cotton (<i>Gossypium hirsutum</i> L.).	45086300	Monsanto Company	OWN	

FAITS INTÉRESSANTS
LE SAVIEZ-VOUS?

// Par exemple, lorsque EPA décide que le PIP présent dans le produit agricole n'implique aucun danger pour l'être humain ou l'animal, ils accordent une exemption aux exigences réglementaires prévues concernant la limite maximale de résidus (MRL) ou le taux maximum de PIP.

Ce tableau est un exemple de liste de référence soumise à l'EPA. L'essentiel d'une

FAITS INTÉRESSANTS
LE SAVIEZ-VOUS?

- // EPA réglemente les plantes GM avec « traits » qui protègent les plantes de nuisibles agricoles, également connus comme Protecteurs-Incorporés-aux plantes (PIP).
- // EPA ne réglemente pas les plantes GM tolérantes aux herbicides.
- // L'EPA publie alors un résumé d'agence sur l'évaluation du risque et les décisions réglementaires liées aux PIPs.
- // Ces résumés sont disponibles sur [le site de l'EPA](#).

soumission EPA se résume à la liste de références (fait également référence à la matrice de données), qui liste tous les documents utilisés afin que l'EPA puisse évaluer la sécurité des Protecteurs-Incorporés-aux plantes (PIP), établir une exonération permanente des prérequis à la tolérance, et délivrer une homologation commerciale pour le PIP.