

Bp number: 99-095-16n

App number: 99-254XRAB  
 Received: 4/05/99  
 Institution: Monsanto  
 Recipient: Wheat  
 Status: Pending  
 Effective date: 5/05/99  
 Phenotype: HT - Glyphosate tolerant  
 Comments:  
 Resp person: (b) (6), (b) (7)(C)  
 Parsed name: (b) (6), (b) (7)(C)  
 Address1: Monsanto Company  
 Address2: 700 Chesterfield Parkway North  
 Address3:  
 Address4:  
 City/State/Zip: St. Louis, MO 63198  
 Telephone: (b) (6), (b) (7)(C) Fax: 314-737-7085

- |  | Initial         | Date                     |
|--|-----------------|--------------------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ <i>lll</i> ]  | [ 4/8/99 ]               |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist               | [ <i>XZH</i> ]* | [ 4/9/99 ]*              |
| 3. <input checked="" type="checkbox"/> Letter of notification to State         | [ <i>lab</i> ]  | [ 4/9/99 ]* <i>fed X</i> |
| 4. <input type="checkbox"/> State response                                     |                 |                          |

	O/d	Loc	Site	Reg		
Interstate	*Dest*	CA	*	*WR	*	[ ]
Interstate	*Dest*	MO	*	*SCR	*	[ ]
Interstate	*Orig*	CA	*	*WR	*	[ ]
Interstate	*Orig*	MO	*	*SCR	*	[ ]
Release	*	CA	*	1*WR	*	[ ]

- |  |                |                        |
|--|----------------|------------------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database                         | [ <i>lll</i> ] | [ 4/9/99 ]             |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [ <i>lgs</i> ] | [ 5/3/99 ]* <i>BAX</i> |
| 7. <input checked="" type="checkbox"/> Enter final data into database                    | [ <i>lgs</i> ] | [ 5/4/99 ]             |

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**CONFIDENTIAL**

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
http://www.monsanto.com

Monsanto Reference ID  
99-254XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Mar 31, 1999

99-095-16n

- 1. **USDA Reference Number**
- 2. **Applicant Reference Number**
- 3. **Applicant/Responsible Party**

99-254XRAB

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Chesterfield Village Pkwy N  
St. Louis, MO 63198

**4. Duration of Introduction**

Interstate Movement and Release      Apr 30, 1999 - Apr 29, 2000

**5. Recipient**                      Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:**              HT  
**Phenotype:**                          glyphosate-tolerant

(b) (6), (b)

# CONFIDENTIAL

Monsanto Reference ID  
99-254XRAB

**designation of transformed line:** 25372, 25397, 25463

**Constructs:** PV-TXGT05

**genotype:**

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ (b) (4) ] - CBI CBI
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: CMoVa/I5 -- [ (b) (4) ] - CBI CBI
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID  
99-254XRAB

**7. Mode of Transformation** Particle Bombardment

**8. Introduction** Interstate Movement and Release

Up to 55 pounds of seed and plant material to each location. After harvest, up to 550 pounds of seed and plant material to be returned to each location.

**ORIGIN:** CA MO **DESTINATION:** CA MO

**Ship From:**

CA

(b) (4), Santa Cruz County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) Santa Cruz  
County, CA, (b) (6), (b) (7)(C), (b) (4)

(b) (4), Contra Costa County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) Contra Costa  
County, CA, (b) (6), (b) (7)(C), (b) (4)

MO

(b) (4) St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) St. Louis  
County, MO, (b) (6), (b) (7)(C), (b) (4)

(b) (4) Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) St.  
Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

**Ship To:**

CA

# CONFIDENTIAL

Monsanto Reference ID  
99-254XRAB

\* [REDACTED] (b) (4), Contra Costa County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED] Contra  
Costa County, CA, (b) (6), (b) (7)(C) U.S.A., (b) (6), (b) (7)(C), (b) (4)

\* [REDACTED] (b) (4), Santa Cruz County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4), Santa  
Cruz County, CA, (b) (6), (b) (7)(C) U.S.A., (b) (6), (b) (7)(C), (b) (4)

## MO

[REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

[REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED], St.  
Louis County, MO (b) (6), (b) (7)(C), (b) (4)

## Release Sites:

### NUMBER OF STATES/TERRITORIES AND SITES:

CA (1)

### CA

\* [REDACTED] (b) (4) Santa Cruz County, CA acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4),  
Santa Cruz County, CA. Contact [REDACTED] (b) (6), (b) (7)(C), (b) (4)

MONSANTO



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PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-254XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company  
Mar 31, 1999

## CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into potatoes and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

### **Gene Description**

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant potatoes for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, And Expressed Traits**

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents *for* the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **Identity And Characteristics Of Donor Organism**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms for tomatoes has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identity of Recipient Cultivars**

Some of the potato cultivars are claimed as confidential because disclosure of the variety name would identify a confidential business partner which has not been publicly announced.

### **Identification of Items claimed as Confidential Business Information**

Items claimed as CBI as so indicated in the text as follows: [ CBI - Deleted ]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[ ]", as labeled as CBI.



Monsanto Reference ID  
99-254XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Mar 31, 1999

99-095-16n

- 1. USDA Reference Number
- 2. Applicant Reference Number
- 3. Applicant/Responsible Party

99-254XRAB

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 314-737-7085

EEmail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Chesterfield Village Pkwy N  
St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release Apr 30, 1999 - Apr 29, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate-tolerant

(b) (6), (b) (7)(C)

# CBI - DELETED

Monsanto Reference ID  
99-254XRAB

**designation of transformed line:** 25372, 25397, 25463

**Constructs:** PV-TXGT05

**genotype:**

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: CMoVa/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

# CBI - DELETED

Monsanto Reference ID  
99-254XRAB

**7. Mode of Transformation** Particle Bombardment

**8. Introduction** Interstate Movement and Release

Up to 55 pounds of seed and plant material to each location. After harvest, up to 550 pounds of seed and plant material to be returned to each location.

**ORIGIN:** CA MO **DESTINATION:** CA MO

**Ship From:**

CA

(b) (4)

Santa Cruz County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4), Santa Cruz County, CA, (b) (6), (b) (7)(C), (b) (4)

(b) (4)

, Contra Costa County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4), Contra Costa County, CA, (b) (6), (b) (7)(C), (b) (4)

MO

(b) (4)

St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4), St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

(b) (4)

St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4), St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

**Ship To:**

CA

# CBI - DELETED

Monsanto Reference ID  
99-254XRAB

\* (b) (4) , Contra Costa County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) , Contra  
Costa County, CA, (b) (6), (b) (7)(C) U.S.A., (b) (6), (b) (7)(C), (b) (4)

\* (b) (4) Santa Cruz County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) , Santa  
Cruz County, CA, (b) (6), (b) (7)(C) U.S.A., (b) (6), (b) (7)(C), (b) (4)

## MO

\* (b) (4) St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)  
(b) (6), (b) (7)(C) , St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

\* (b) (4) St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) , St.  
Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

## Release Sites:

### NUMBER OF STATES/TERRITORIES AND SITES:

CA (1)

CA

\* (b) (4) Santa Cruz County, CA acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4)  
Santa Cruz County, CA. Contact: (b) (6), (b) (7)(C), (b) (4)



**CBI - DELETED**

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID  
99-254XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Mar 31, 1999

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Monsanto Reference ID  
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Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Mar 31, 1999

99-095-16n

- 1. **USDA Reference Number**
- 2. **Applicant Reference Number**
- 3. **Applicant/Responsible Party**

99-254XRAB

(b) (6), (b) (7)(C)

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FAX 314-737-7085

EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Chesterfield Village Pkwy N  
St. Louis, MO 63198

4. **Duration of Introduction**

Interstate Movement and Release Apr 30, 1999 - Apr 29, 2000

5. **Recipient** Wheat, Triticum aestivum

6. **Regulated Article**

**Phenotypic Category:** HT  
**Phenotype:** glyphosate-tolerant  
Bob White

# CBI - DELETED

Monsanto Reference ID  
99-254XRAB

designation of transformed line: 25372, 25397, 25463

Constructs: PV-TXGT05

genotype:

#### Gene of Interest

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.
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#### Gene of Interest

- \* Promoter: CMoVa/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID  
99-254XRAB

7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Up to 55 pounds of seed and plant material to each location. After harvest, up to 550 pounds of seed and plant material to be returned to each location.

ORIGIN: CA MO DESTINATION: CA MO

Ship From:

CA

(b) (4)

Santa Cruz County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) Santa Cruz  
County, CA, (b) (6), (b) (7)(C), (b) (4)

(b) (4)

Contra Costa County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) Contra Costa  
County, CA, (b) (6), (b) (7)(C), (b) (4)

MO

(b) (4)

St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) St. Louis  
County, MO, (b) (6), (b) (7)(C), (b) (4)

(b) (4)

St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) St.  
Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

Ship To:

CA

# CBI - DELETED

Monsanto Reference ID  
99-254XRAB

\* (b) (4) Contra Costa County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4), Contra  
Costa County, CA, [REDACTED] U.S.A., (b) (6), (b) (7)(C), (b) (4)

\* (b) (4) Santa Cruz County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4), Santa  
Cruz County, CA, [REDACTED] U.S.A., (b) (6), (b) (7)(C), (b) (4)

## MO

\* (b) (4) St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

\* ] (b) (4) ,St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4) St.  
Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

## Release Sites:

### NUMBER OF STATES/TERRITORIES AND SITES:

CA (1)

CA

\* (b) (4) , Santa Cruz County, CA acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
Santa Cruz County, CA. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID  
99-254XRAB

### 9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

**(b) (6), (b) (7)(C)**

Monsanto Company

Mar 31, 1999

file copy

Ms. Barbara Hass, State Regulatory Official  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

April 5, 1999

Dear Ms. Hass:

Enclosed is notification 99-095-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-095-16n	Applicant #:	99-254XRAB
Received:	April 5, 1999	Effective:	May 5, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MO		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

OR120018\_BR\_012571

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

April 5, 1999

Dear Mr. Brown:

Enclosed is notification 99-095-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-095-16n	Applicant #:	99-254XRAB
Received:	April 5, 1999	Effective:	May 5, 1999
Institution:	Monsanto	Recipient:	Wheat
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Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

OR120018\_BR\_012572



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Ms. Barbara Hass, State Regulatory Official  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

April 5, 1999

Dear Ms. Hass:

Enclosed is notification 99-095-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-095-16n	Applicant #:	99-254XRAB
Received:	April 5, 1999	Effective:	May 5, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MO		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

**(b) (6), (b) (7)(C)**

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.  
 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Barbara I Hass (916) 654-1017

Signature: **(b) (6), (b) (7)(C)**

Date: April 14, 1999

State: California

4-15-99



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Rivergate, MO 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

April 5, 1999

Dear Mr. Brown:

Enclosed is notification 99-095-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-095-16n	Applicant #:	99-254XRAB
Received:	April 5, 1999	Effective:	May 5, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA MO		
Release destination:	CA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 4/13/99

State: MO



May 3, 1999

(b) (6), (b) (7)(C)  
Monsanto Company  
700 Chesterfield Parkway N  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C) :

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after May 5, 1999.

**Interstate movement and release**  
**Notification no. 99-095-16n (99-254XRAB)**  
**Regulated article - Wheat**  
**Destination(s) - California, Missouri**

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official(s), and the Regional Program Manager(s), (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations  
Scientific Services  
Plant Protection and Quarantine

Enclosure

cc:  
B. Hass, California Dept. of Food and Agric., Sacramento, CA  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
R. Stoaks, PPQ, WR, Sacramento, CA  
D. DeWeese, PPQ, SCR, Brownsville, TX  
File number 99-095-16n

OR120018\_BR\_012575

Confirmation Report-Memory Send

Time : 05-06-99 04:50pm  
Tel line 1 : +3017348910  
Tel line 2 : +  
Name : USDA

Job number : 884  
Date : 05-06 04:49pm  
To : 913147377085  
Document Pages : 02  
Start time : 05-06 04:49pm  
End time : 05-06 04:50pm  
Pages sent : 02  
Job number : 884

\*\*\* SEND SUCCESSFUL \*\*\*



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

May 6, 1999

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy N  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after May 6, 1999.

Interstate movement and Release  
Notification no. 99-075-03a (99-225SRAD)  
Regulated article - Cotton  
Destinations - Alabama, Missouri, Mississippi, North Carolina, Texas

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

The State of Mississippi require cotton seed moving from a Pink Bollworm regulated area move under a state or federal certificate.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations  
Scientific Services  
Plant Protection and Quarantine

Enclosure

- cc:
- G. Karr, Alabama Dept. of Agric. and Industries, Montgomery, AL
- M. Brown, Missouri Dept. of Agric., Jefferson City, MO
- E. Dyess, Mississippi Dept. of Agric. and Commerce, Mississippi State, MS
- S. Baker, North Carolina Dept. of Agric., Raleigh, NC
- T. Mitchell, Texas Dept. of Agric., Austin, TX
- S. Wood, PPQ, SER, Raleigh, NC
- D. Dewese, PPQ, SCK, Brownsville, TX



APIS - Protecting American Agriculture

An Equal Opportunity Employer

1999 Wheat Field Test Report  
USDA # 99-095-16n Monsanto # 99-254XRAB

(b) (6), (b) (7)(C)

October 3, 2000

Monsanto Company

Location

(b) (4)

County

Santa Cruz

State

CA

Santa Cruz, CA

Planting Date: May 17, 1999

Harvest Date: June 21, 1999

Destruct Date (if not harvested): October 5, 1999 wheat stubble removed

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Field Monitoring for Plant Stand: (b) (4)

Disposition of the seed: (b) (4)

Results: (b) (4)

MONSANTO

Food · Health · Hope



December 8, 2000

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

Ms. Dianne Hatmaker  
Animal and Plant Health Inspection Services  
Biotechnology and Scientific Services  
4700 River Road, Unit 147  
Riverdale, MD

Dear Ms. Hatmaker;

Field releases for the following USDA wheat notifications have been completed and we are now submitting final reports as required. Please find reports for:

<u>USDA Number</u>	<u>Monsanto number</u>
98-333-06n	98-040XR
98-035-04n	98-042XR
98-224-03n	98-313XR
98-229-11n	98-324XRAB
98-261-03n	98-382XRAB
98-261-04n	98-383XRAB
99-039-13n	99-053XRAB
99-039-14n	99-054XRAB
99-047-09n	99-011XR
99-047-11n	99-013XR
99-048-16n	99-094XRA
99-064-15n	99-148XR
99-064-18n	99-144XR
99-092-04n	99-240XRAB
99-092-05n	99-241XRAB
99-095-16n	99-254XRAB
99-105-03n	99-256XRAB
99-126-12n	99-410XRAB
99-130-03n	99-474XRAB

OR120018\_BR\_012578

MONSANTO

*Food · Health · Hope*



If you have any questions concerning these reports, please do not hesitate to contact me at (b) (6), (b) (7)(C)

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

Sincerely,

(b) (6), (b) (7)(C)

Bp number: 99-105-03n

App number: 99-256XRAB  
 Received: 4/15/99  
 Institution: Monsanto  
 Recipient: Wheat  
 Status: Pending  
 Effective date: 5/15/99  
 Phenotype: HT - Glyphosate tolerant  
 Comments:  
 Resp person: (b) (6), (b) (7)(C)  
 Parsed name: (b) (6), (b) (7)(C) (b) (6), (b) (7)(C)  
 Address1: Monsanto Company  
 Address2: 700 Chesterfield Parkway North  
 Address3:  
 Address4:  
 City/State/Zip: St. Louis, MO 63198  
 Telephone: (b) (6), (b) (7)(C) Fax: 314-737-7085

- |  | Initial          | Date         |
|--|------------------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ <i>hll</i> ]   | [ 4/16/99 ]  |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist               | [ <i>smk</i> * ] | [ 4/19/99* ] |
| 3. <input checked="" type="checkbox"/> Letter of notification to State         | [ <i>Bbs</i> ]   | [ 4/21/99 ]* |
| 4. <input type="checkbox"/> State response                                     |                  |              |

	O/d	Loc	Site	Reg		
Interstate	*Dest*	MO	*	*SCR	*	[ ]
Interstate	*Dest*	MT	*	*WR	*	[ ]
Interstate	*Orig*	MO	*	*SCR	*	[ ]
Interstate	*Orig*	MT	*	*WR	*	[ ]
Release	*	*MT	*	1*WR	*	[ ]

- |  |                |              |
|--|----------------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database                         | [ <i>hll</i> ] | [ 4/19/99 ]  |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [ <i>bgs</i> ] | [ 5/10/99 ]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database                    | [ <i>bgs</i> ] | [ 5/11/99 ]  |

*5/11/99 Hand-let. by*

(b) (6), (b) (7)(C)

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**CONFIDENTIAL**

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

http://www.monsanto.com

Monsanto Reference ID  
99-256XRAB

Mar 31, 1999

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

99-105-03n

**1. USDA Reference Number**

**2. Applicant Reference Number**

99-256XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C) 5

(b) (6), (b) (7)(C)  
(b) (6), (b) (7)(C)

FAX

314-737-7085

Monsanto Company  
700 Chesterfield Village Pkwy N  
St. Louis, MO 63198

EMail

(b) (6), (b) (7)(C) @monsanto.com

**4. Duration of Introduction**

Interstate Movement and Release      Apr 30, 1999   -   Apr 29, 2000

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:**

HT

**Phenotype:**

glyphosate-tolerant

Cultivar(s)/Variety: Bobwhite

# CONFIDENTIAL

Monsanto Reference ID  
99-256XRAB

**designation of transformed line:** TA-S1087, TA-S1102, TA-S1711

**Constructs:** PV-TXGT10

**genotype:**

**Gene of Interest**

\* Promoter: CMoVa/I2 -- [REDACTED] (b) (4) ] - CBI

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

\* Promoter: CMP3/I5 -- [REDACTED] (b) (4) ] - CBI

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

# CONFIDENTIAL

Monsanto Reference ID  
99-256XRAB

designation of transformed line: 35710, 35845

Constructs: PV-TXGT12

genotype:

**Gene of Interest**

\* Promoter: MP4 -- [REDACTED] (b) (4) ] - CBI CBI

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: M1 -- [REDACTED] (b) (4) ] - CBI CBI

**Gene of Interest**

\* Promoter: CMP 3/I5 -- [REDACTED] (b) (4) ] - CBI CBI

\* Gene: CTP7-CP4 -- [REDACTED] (b) (4) ] - CBI CBI

\* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

# CONFIDENTIAL

Monsanto Reference ID  
99-256XRAB

**designation of transformed line:** TA-S537

**Constructs:** PV-TXGT13

**genotype:**

**Gene of Interest**

\* Promoter: MP4 -- [REDACTED] (b) (4) ] - CBI

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: M1 3' -- [REDACTED] (b) (4) ] - CBI

# CONFIDENTIAL

Monsanto Reference ID  
99-256XRAB

**designation of transformed line:** TA-S2744, TA-S2747

**Constructs:** PV-TXGT15

**genotype:**

**Gene of Interest**

- \* Promoter: CMP 3/I5 -- [REDACTED] (b) (4) ] - CBI *CBI*
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: MP4 -- [REDACTED] (b) (4) ] - CBI *CBI*
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 3' -- [REDACTED] (b) (4) ] - CBI *CBI*

# CONFIDENTIAL

Monsanto Reference ID  
99-256XRAB

7. **Mode of Transformation** Disarmed *Agrobacterium tumefaciens*  
8. **Introduction** Interstate Movement and Release

Up to 80 pounds of wheat seed to each location. After harvest, up to 800 pounds to be returned to each location.

**ORIGIN:** MO MT **DESTINATION:** MO MT

**Ship From:**

MO

\* [REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C), St. Louis County, MO, (b) (4), (b) (6), (b) (7)(C)

MT

\* [REDACTED] (b) (4), (b) (6), (b) (7)(C), Pondera County, MT

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C), Pondera County, MT, (b) (4), (b) (6), (b) (7)(C)

**Ship To:**

MO

[REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C), [REDACTED], St. Louis County, MO, (b) (4), (b) (6), (b) (7)(C)

MT

\* [REDACTED] (b) (4), (b) (6), (b) (7)(C), Pondera County, MT

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C), Pondera County, MT, (b) (4), (b) (6), (b) (7)(C)

**Release Sites:**

*CONFIDENTIAL*

Monsanto Reference ID  
99-256XRAB

**NUMBER OF STATES/TERRITORIES AND SITES:**

MT (1)

*MT*

\* Doug Ryerson Farm, Pondera County, MT up to 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) Pondera  
County, MT. Contact: (b) (4), (b) (6), (b) (7)(C)

MONSANTO

Food · Health · Hope



*CONFIDENTIAL*

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-256XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company  
Mar 31, 1999

## CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

### LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.<sup>1</sup>

#### GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

<sup>1</sup> In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS**

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



CBI - DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-256XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Mar 31, 1999

99-105-03n

1. USDA Reference Number
2. Applicant Reference Number
3. Applicant/Responsible Party

99-256XRAB

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

FAX 314-737-7085

EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Chesterfield Village Pkwy N  
St. Louis, MO 63198

4. Duration of Introduction

Interstate Movement and Release Apr 30, 1999 - Apr 29, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT  
Phenotype: glyphosate-tolerant  
Cultivar(s)/Variety: Bobwhite

# CBI - DELETED

Monsanto Reference ID  
99-256XRAB

**designation of transformed line:** TA-S1087, TA-S1102, TA-S1711

**Constructs:** PV-TXGT10

**genotype:**

**Gene of Interest**

- \* Promoter: CMoVa/I2 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

# CBI - DELETED

Monsanto Reference ID  
99-256XRAB

**designation of transformed line:** 35710, 35845

**Constructs:** PV-TXGT12

**genotype:**

**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.
- \* Terminator: M1 -- [ CBI Deleted ]

**Gene of Interest**

- \* Promoter: CMP 3/I5 -- [ CBI Deleted ]
- \* Gene: CTP7-CP4 -- [ CBI Deleted ]
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

# CBI - DELETED

Monsanto Reference ID  
99-256XRAB

**designation of transformed line:** TA-S537

**Constructs:** PV-TXGT13

**genotype:**

**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 3' -- [ CBI Deleted ]

# CBI - DELETED

Monsanto Reference ID  
99-256XRAB

**designation of transformed line:** TA-S2744, TA-S2747

**Constructs:** PV-TXGT15

**genotype:**

**Gene of Interest**

- \* Promoter: CMP 3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 3' -- [ CBI Deleted ]



# CBI - DELETED

Monsanto Reference ID  
99-256XRAB

**NUMBER OF STATES/TERRITORIES AND SITES:**

**MT (1)**

*MT*

\* (b) (6), (b) (7)(C), (b) (4), Pondera County, MT up to 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4) Pondera  
County, MT. Contact: (b) (6), (b) (7)(C), (b) (4)

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID  
99-256XRAB

### 9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Mar 31, 1999

# MONSANTO

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MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-256XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Mar 31, 1999

99-105-03n

1. **USDA Reference Number**
2. **Applicant Reference Number**
3. **Applicant/Responsible Party**

99-256XRAB

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

314-737-7085

(b) (6), (b) (7)(C)

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Village Pkwy N

St. Louis, MO 63198

4. **Duration of Introduction**

Interstate Movement and Release      Apr 30, 1999 - Apr 29, 2000

5. **Recipient**      Wheat, Triticum aestivum

6. **Regulated Article**

**Phenotypic Category:**      HT

**Phenotype:**      glyphosate-tolerant

**Cultivar(s)/Variety:** Bobwhite

CBI - DELETED

Monsanto Reference ID  
99-256XRAB

**designation of transformed line:** TA-S1087, TA-S1102, TA-S1711

**Constructs:** PV-TXGT10

**genotype:**

**Gene of Interest**

- \* Promoter: CMoVa/I2 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID  
99-256XRAB

designation of transformed line: 35710, 35845

**Constructs:** PV-TXGT12

**genotype:**

**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 -- [ CBI Deleted ]

**Gene of Interest**

- \* Promoter: CMP 3/15 -- [ CBI Deleted ]
- \* Gene: CTP7-CP4 -- [ CBI Deleted ]
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID  
99-256XRAB

designation of transformed line: TA-S537

Constructs: PV-TXGT13

genotype:

**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 3' -- [ CBI Deleted ]

CBI - DELETED

Monsanto Reference ID  
99-256XRAB

**designation of transformed line:** TA-S2744, TA-S2747

**Constructs:** PV-TXGT15

**genotype:**

**Gene of Interest**

- \* Promoter: CMP 3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2 or 21), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 3' -- [ CBI Deleted ]

CBI - DELETED

Monsanto Reference ID  
99-256XRAB

7. **Mode of Transformation** Disarmed *Agrobacterium tumefaciens*

8. **Introduction** Interstate Movement and Release

Up to 80 pounds of wheat seed to each location. After harvest, up to 800 pounds to be returned to each location.

**ORIGIN:** MO MT **DESTINATION:** MO MT

**Ship From:**

MO

(b) (4)

St. Louis County, MO 63198

CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED], St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

MT

(b) (6), (b) (7)(C), (b) (4)

Pondera County, MT

CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED], Pondera County, MT, (b) (6), (b) (7)(C), (b) (4)

**Ship To:**

MO

\* 1

(b) (4)

St. Louis County, MO 63198

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

MT

(b) (6), (b) (7)(C), (b) (4)

Pondera County, MT

CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED], Pondera County, MT, (b) (6), (b) (7)(C), (b) (4)

**Release Sites:**

CBI - DELETED

Monsanto Reference ID  
99-256XRAB

**NUMBER OF STATES/TERRITORIES AND SITES:**

**MT (1)**

*MT*

\* (b) (6), (b) (7)(C), (b) (4) Pondera County, MT up to 2 acres.

RESPONSIBLE PERSON/RESEARCHER (b) (6), (b) (7)(C), (b) (4) [REDACTED], Pondera  
County, MT. Contact: (b) (6), (b) (7)(C), (b) (4) [REDACTED]

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MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-256XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Mar 31, 1999

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

April 15, 1999

Dear Mr. Brown:

Enclosed is notification 99-105-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-105-03n	Applicant #:	99-256XRAB
Received:	April 15, 1999	Effective:	May 15, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

file copy

Dr. Gary Gingery, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

April 15, 1999

Dear Dr. Gingery:

Enclosed is notification 99-105-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-105-03n	Applicant #:	99-256XRAB
Received:	April 15, 1999	Effective:	May 15, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
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Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale MD 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

April 15, 1999

Dear Mr. Brown:

Enclosed is notification 99-105-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-105-03n	Applicant #:	99-256XRAB
Received:	April 15, 1999	Effective:	May 15, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

**(b) (6), (b) (7)(C)**

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: **(b) (6), (b) (7)(C)**

Date: 4/26/99

State: MO





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale MD 20737

Dr. Gary Gingery, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

April 15, 1999

Dear Dr. Gingery:

Enclosed is notification 99-105-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-105-03n	Applicant #:	99-256XRAB
Received:	April 15, 1999	Effective:	May 15, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori M. Witham

Signature: (b) (6), (b) (7)(C)

Date: April 22, 1999

State: Montana

May 11, 1999

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Village Parkway N  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C):

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after May 15, 1999.

**Interstate movement and release**  
**Notification no. 99-105-03n (99-256XRAB)**  
**Regulated article - Wheat**  
**Destination(s) - Missouri, Montana**

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official(s), and the Regional Program Manager(s), (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations  
Scientific Services  
Plant Protection and Quarantine

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
G. Gingery, Montana Dept. of Agric., Helena, MT  
D. DeWeese, PPQ, SCR, Brownsville, TX  
R. Stoaks, PPQ, WR, Sacramento, CA  
File number 99-105-03n

OR120018\_BR\_012613

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December 8, 2000

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

Ms. Dianne Hatmaker  
Animal and Plant Health Inspection Services  
Biotechnology and Scientific Services  
4700 River Road, Unit 147  
Riverdale, MD

Dear Ms. Hatmaker;

Field releases for the following USDA wheat notifications have been completed and we are now submitting final reports as required. Please find reports for:

**USDA Number**

**Monsanto number**

98-333-06n	98-040XR
98-035-04n	98-042XR
98-224-03n	98-313XR
98-229-11n	98-324XRAB
98-261-03n	98-382XRAB
98-261-04n	98-383XRAB
99-039-13n	99-053XRAB
99-039-14n	99-054XRAB
99-047-09n	99-011XR
99-047-11n	99-013XR
99-048-16n	99-094XRA
99-064-15n	99-148XR
99-064-18n	99-144XR
99-092-04n	99-240XRAB
99-092-05n	99-241XRAB
99-095-16n	99-254XRAB
99-105-03n	99-256XRAB
99-126-12n	99-410XRAB
99-130-03n	99-474XRAB

OR120018\_BR\_012614

MONSANTO

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If you have any questions concerning these reports, please do not hesitate to contact me at (b) (6), (b) (7)(C).

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63108  
PHONE (314) 694-1000  
FAX (636) 737-7085  
<http://www.monsanto.com>

Sincerely,

(b) (6), (b) (7)(C)

1999 Wheat Field Test Report  
USDA # 99-105-03n Monsanto # 99-256XRAB

(b) (6), (b) (7)(C)

October 2, 2000

Monsanto Company

Location

(b) (4)

County

Pondera

State

MT

Pondera, MT

Planting Date: May 17, 1999

Harvest Date: August 26, 1999

Vector Constructs/Line Numbers Planted:

(b) (4)

Purpose of Field Trial:

(b) (4)

Field Monitoring for Disease Susceptibility:

(b) (4)

Field Monitoring for Insect Susceptibility:

(b) (4)

Field Monitoring for Plant Growth Characteristics:

(b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

Disposition of the seed:

(b) (4)



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**CONFIDENTIAL**

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
http://www.monsanto.com

Monsanto Reference ID  
99-675XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 07, 1999

99-251-03n

- 1. **USDA Reference Number**
- 2. **Applicant Reference Number**
- 3. **Applicant/Responsible Party**

99-675XRAB

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)  
 FAX 636/737-7085  
 EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Cheserfield Parkway North  
St. Louis, MO

**4. Duration of Introduction**

Interstate Movement and Release Oct 07, 1999 - Oct 06, 2000

**5. Recipient** Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT  
**Phenotype:** glyphosate tolerant  
 Cultivar/Varieties Bobwhite and B1175 or B1183

# CONFIDENTIAL

Monsanto Reference ID  
99-675XRAB

**designation of transformed line:** 25372, 25397

**Constructs:** PV-TXGT05

**genotype:**

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [REDACTED] (b) (4)  
[REDACTED] - CBI *CBI*
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: CMoVa/I5 -- [REDACTED] (b) (4)  
[REDACTED] - CBI *CBI*
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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Monsanto Reference ID  
99-675XRAB

- 7. **Mode of Transformation**      Particle Bombardment
- 8. **Introduction**                      Interstate Movement and Release

Ship up to 2200 pounds wheat seed before and after harvest

<b>ORIGIN:</b>		<b>DESTINATION:</b>	
CO	MT	CO	MT
WA		WA	

**Ship From:**

*CO*

(b) (4), Yuma County, CO

CONTACT: (b) (4), (b) (6), (b) (7)(C) [redacted] Yuma County, CO

*MT*

(b) (4), Cascade County, MT 59404

CONTACT: (b) (4), (b) (6), (b) (7)(C) [redacted], Cascade County,  
MT; (b) (4), (b) (6), (b) (7)(C) [redacted]

*WA*

\* (b) (4), Walla Walla County, WA 99362

CONTACT: (b) (4), (b) (6), (b) (7)(C) [redacted], Benton County, WA,  
(b) (4), (b) (6), (b) (7)(C) [redacted]

**Ship To:**

*CO*

\* (b) (4), Yuma County, CO

CONTACT: (b) (4), (b) (6), (b) (7)(C) [redacted], Yuma County, CO

# CONFIDENTIAL

Monsanto Reference ID  
99-675XRAB

## MT

\* [REDACTED], Cascade County, MT (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) [REDACTED], Cascade County,  
MT, (b) (4), (b) (6), (b) (7)(C)

## WA

[REDACTED] (b) (4), Walla Walla County, WA (b) (4)

CONTACT (b) (4), (b) (6), (b) (7)(C) [REDACTED]  
[REDACTED] Walla Walla County, WA, (b) (4), (b) (6), (b) (7)(C)

## Release Sites:

### NUMBER OF STATES/TERRITORIES AND SITES:

CO (1) MT (1) WA (1)

## CO

\* [REDACTED] (b) (4), Yuma County, CO up to 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) [REDACTED], Yuma County,  
CO. Contact: (b) (4), (b) (6), (b) (7)(C)

## MT

\* [REDACTED] (b) (4) Cascade County, MT up to 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) [REDACTED] Cascade  
County, MT. Contact: (b) (4), (b) (6), (b) (7)(C)

## WA

\* [REDACTED] (b) (4), Walla Walla County, WA up to 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) [REDACTED]  
[REDACTED] Walla Walla County, WA. Contact: (b) (4), (b) (6), (b) (7)(C)

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MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-675XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

**(b) (6), (b) (7)(C)**

Monsanto Company  
Sep 07, 1999

## CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, And Expressed Traits**

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **Identity And Characteristics Of Donor Organism**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identity of Recipient Cultivars**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identification of Items claimed as Confidential Business Information**

Items claimed as CBI as so indicated in the text as follows: [ CBI - Deleted ]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[ ]", as labeled as CBI.

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CBI - DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
http://www.monsanto.com

Monsanto Reference ID  
99-675XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 07, 1999

99 - 251 - 03n

- 1. USDA Reference Number
- 2. Applicant Reference Number
- 3. Applicant/Responsible Party

99-675XRAB

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)  
 FAX 636/737-7085  
 EMail (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Cheserfield Parkway North  
St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release Oct 07, 1999 - Oct 06, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT  
 Phenotype: glyphosate tolerant  
 Cultivar/Varieties Bobwhite and B1175 or B1183

# CBI - DELETED

Monsanto Reference ID  
99-675XRAB

**designation of transformed line:** 25372, 25397

**Constructs:** PV-TXGT05

**genotype:**

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: CMoVa/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID  
99-675XRAB

- 7. **Mode of Transformation**      Particle Bombardment
- 8. **Introduction**                      Interstate Movement and Release

Ship up to 2200 pounds wheat seed before and after harvest

<b>ORIGIN:</b>		<b>DESTINATION:</b>	
CO	MT	CO	MT
WA		WA	

**Ship From:**

*CO*

\* (b) (4) , Yuma County, CO

CONTACT: (b) (6), (b) (7)(C), (b) (4) , Yuma County, CO

*MT*

\* (b) (4) , Cascade County, MT 59404

CONTACT: (b) (6), (b) (7)(C), (b) (4) , Cascade County,  
MT, (b) (6), (b) (7)(C), (b) (4)

*WA*

\* (b) (4) Walla Walla County, WA 99362

CONTACT: (b) (6), (b) (7)(C), (b) (4) Benton County, WA,  
(b) (6), (b) (7)(C), (b) (4)

**Ship To:**

*CO*

\* (b) (4) Yuma County, CO

CONTACT (b) (6), (b) (7)(C), (b) (4) , Yuma County, CO

# CBI - DELETED

Monsanto Reference ID  
99-675XRAB

*MT*

\* (b) (4) , Cascade County, MT (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) ██████████, Cascade County,  
MT, (b) (6), (b) (7)(C), (b) (4)

*WA*

\* (b) (4) Walla Walla County, WA (b) (4)

CONTACT ██████████ (b) (6), (b) (7)(C), (b) (4)  
██████████ Walla Walla County, WA, (b) (6), (b) (7)(C), (b) (4)

## Release Sites:

### NUMBER OF STATES/TERRITORIES AND SITES:

CO (1) MT (1) WA (1)

*CO*

\* (b) (4) , Yuma County, CO up to 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4) Yuma County,  
CO. Contact: (b) (6), (b) (7)(C), (b) (4)

*MT*

\* (b) (4) , Cascade County, MT up to 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4) ██████████, Cascade  
County, MT. Contact: (b) (6), (b) (7)(C), (b) (4)

*WA*

\* (b) (4) , Walla Walla County, WA up to 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4) ██████████  
██████████ Walla Walla County, WA. Contact: (b) (6), (b) (7)(C), (b) (4)

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID  
99-675XRAB

### 9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 07, 1999



CBI - DELETED

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PHONE (314) 694-1000  
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Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 07, 1999

99-251-03n

- 1. USDA Reference Number
- 2. Applicant Reference Number
- 3. Applicant/Responsible Party

99-675XRAB

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EEmail

(b) (6), (b) (7)(C) @monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release Oct 07, 1999 - Oct 06, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate tolerant

Cultivar/Varities Bobwhite and B1175 or B1183

Monsanto Reference ID  
99-675XRAB

**designation of transformed line:** 25372, 25397

**Constructs:** PV-TXGT05

**genotype:**

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.
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**Gene of Interest**

- \* Promoter: CMoVa/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

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CBI - DELETED

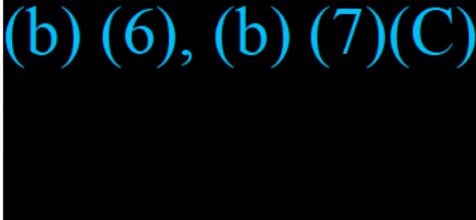
MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-675XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

Sep 07, 1999

file copy

Mr. Mitch Yergert  
Colorado Department of Agriculture  
700 Kipling Street - Suite 4000  
Lakewood, CO 80215-5894

September 9, 1999

Dear Mr. Yergert:

Enclosed is notification 99-251-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number	99-251-03n	Applicant #:	99-675XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MT WA		
Release destination:	CO MT WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

OR120018\_BR\_012634

file copy

Dr. Gary Gingery, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

September 9, 1999

Dear Dr. Gingery:

Enclosed is notification 99-251-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-03n	Applicant #:	99-675XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MT WA		
Release destination:	CO MT WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

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Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

September 9, 1999

Dear Mr. Wessels:

Enclosed is notification 99-251-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-03n	Applicant #:	99-675XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MT WA		
Release destination:	CO MT WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

OR120018\_BR\_012636



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Mitch Yergert  
Colorado Department of Agriculture  
700 Kipling Street - Suite 4000  
Lakewood, CO 80215-5894

September 9, 1999

Dear Mr. Yergert:

Enclosed is notification 99-251-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number	99-251-03n	Applicant #:	99-675XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MT WA		
Release destination:	CO MT WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Blaine Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mitchell Yergert

Signature: \_\_\_\_\_

(b) (6), (b) (7)(C)

Date: September 13, 1999

State: Colorado





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Dr. Gary Gingery, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

September 9, 1999

Dear Dr. Gingery:

Enclosed is notification 99-251-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-03n	Applicant #:	99-675XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MT WA		
Release destination:	CO MT WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori M. Witham

Signature: (b) (6), (b) (7)(C)

Date: September 15, 1999

State: Montana



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MO 20737

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

September 9, 1999

Dear Mr. Wessels:

Enclosed is notification 99-251-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-03n	Applicant #:	99-675XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MT WA		
Release destination:	CO MT WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

**(b) (6), (b) (7)(C)**

B. Diane Macomber, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: **(b) (6), (b) (7)(C)**

Date: 9/10/99

State: WA



September 23, 1999

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy N  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C):

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 8, 1999.

Interstate movement and Release  
Notification no. 99-251-03n (99-675XRAB)  
Regulated article - Wheat  
Destinations - Colorado, Montana, Washington

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations  
Scientific Services  
Plant Protection and Quarantine

Enclosure

cc:

M. Yergert, Colorado Dept. of Agric., Lakewood, CO  
R. Stoaks, PPQ, WR, Sacramento, CA  
File number 99-251-03n

OR120018\_BR\_012640

1999 Wheat Field Test Report  
USDA # 99-251-03n Monsanto # 99-675XRAB

(b) (6), (b) (7)(C)

April 16, 2001

Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
(b) (4)	Yuma	CO
	Cascade	MT
	Walla Walla	WA

Yuma County, CO

Planting Date: October 11, 1999

Destruct /Harvest June 2, 2000

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

Disposition of the seed: (b) (4)

Monitoring for Volunteer Plants: (b) (4)

Cascade County, MT

Planting Date: October 15, 1999

Destruct/ Harvest Date: Trial was destroyed on June 5, 2000.

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

**Walla Walla, WA**

Planting Date: October 25, 2000

Destruct/Harvest Date June 5, 2000.

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Field Monitoring for Plant Stand: (b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

**Walla Walla, WA**

Planting Date: April 4, 2000

Harvest Date: August 9, 2000

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Field Monitoring for Plant Stand: (b) (4)

Disposition of the seed: (b) (4)



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MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-680XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 07, 1999

99 - 251 - 04n

**1. USDA Reference Number**

**2. Applicant Reference Number** 99-680XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX 636/737-7085

Monsanto Company  
700 Cheserfield Parkway North  
St. Louis, MO

EMail (b) (6), (b) (7)(C)@monsanto.com

**4. Duration of Introduction**

Interstate Movement and Release Oct 07, 1999 - Oct 06, 2000

**5. Recipient** Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT  
**Phenotype:** glyphosate tolerant  
Cultivar/ Variety Bobwhite, BW251

# CONFIDENTIAL

Monsanto Reference ID  
99-680XRAB

**designation of transformed line:** 33391, 33456, 33463

**Constructs:** PV-TXGT10

**genotype:**

**Gene of Interest**

\* Promoter: CMoVa/I2 -- [REDACTED] (b) (4)

CBI

] - CBI

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

\* Promoter: CMP3/I5 -- [REDACTED] (b) (4)

CBI

- CBI

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

# CONFIDENTIAL

Monsanto Reference ID  
99-680XRAB

**designation of transformed line:** TA S1249, TA S1255, TA S1264, TA S1266, TA S1269, TA S1276,  
TA S1278, TA S1364, TA S1378, TA S1455, TA S1465, TA S1472,  
TA S1614, TA S1615, TA S2022, TA S2027

**Constructs:** PV-TXGT11

**genotype:**

**Gene of Interest**

\* Promoter: CMP 3/I5 -- [REDACTED] (b) (4) CBI  
[REDACTED] - CBI

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: NOS 3' +2 -- [REDACTED] (b) (4) CBI  
[REDACTED] - CBI

**Gene of Interest**

\* Promoter: CMoVa/I5 + leader1 -- [REDACTED] (b) (4) CBI  
[REDACTED] - CBI

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: M1 3' -- [REDACTED] (b) (4) CBI  
[REDACTED] - CBI

# CONFIDENTIAL

Monsanto Reference ID  
99-680XRAB

**designation of transformed line:** 33512, 35710, 35845

**Constructs:** PV-TXGT12

**genotype:**

**Gene of Interest**

\* Promoter: MP4 -- [REDACTED] (b) (4) ] - CBI *CBI*

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: M1 -- [REDACTED] (b) (4) - CBI *CBI*

**Gene of Interest**

\* Promoter: CMP 3/15 -- [REDACTED] (b) (4) - CBI *CBI*

\* Gene: CTP7-CP4 -- [REDACTED] (b) (4) CBI *CBI*

\* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

# CONFIDENTIAL

Monsanto Reference ID  
99-680XRAB

**designation of transformed line:** TA S537, TA S317, TA S342, TA S621, TA S635, TA S1081, TA S2520, TA S4490, TA S5070, TA S5450, TA S5451

**Constructs:** PV-TXGT13

**genotype:**

**Gene of Interest**

\* Promoter: MP4 -- [REDACTED] (b) (4) ] - CBI

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: M1 3' -- [REDACTED] (b) (4) - CBI

# CONFIDENTIAL

Monsanto Reference ID  
99-680XRAB

**designation of transformed line:** TA S2744, TA S2747

**Constructs:** PV-TXGT15

**genotype:**

**Gene of Interest**

- \* Promoter: CMP 3/I5 -- [REDACTED] (b) (4) ] - CBI *CBI*
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: MP4 -- [REDACTED] (b) (4) - CBI *CBI*
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 3' -- [REDACTED] (b) (4) - CBI *CBI*

# CONFIDENTIAL

Monsanto Reference ID  
99-680XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens  
**8. Introduction** Interstate Movement and Release

Ship up to 600 pounds of wheat seed

**ORIGIN:**  
AZ MO **DESTINATION:**  
AZ MO

**Ship From:**

AZ

\* [REDACTED] (b) (4), Yuma County, AZ

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
Yuma County, AZ, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

MO

[REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
[REDACTED] St. Louis County, MO, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

**Ship To:**

AZ

\* [REDACTED] (b) (4) Yuma County, AZ

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C), Yuma  
County, AZ, [REDACTED] (b) (4), (b) (6), (b) (7)(C)

MO

\* [REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
St. Louis County, MO, [REDACTED] (b) (4), (b) (6), (b) (7)(C) U.S.A., [REDACTED] (b) (4), (b) (6), (b) (7)(C)

**Release Sites:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

*CONFIDENTIAL*

Monsanto Reference ID  
99-680XRAB

AZ (1)

AZ

\* [REDACTED] (b) (4), Yuma County, AZ up to 4 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

[REDACTED] Yuma County, AZ. Contact: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

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MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63108  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-680XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

**(b) (6), (b) (7)(C)**

Monsanto Company  
Sep 07, 1999

## CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, And Expressed Traits**

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents *for* the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **Identity And Characteristics Of Donor Organism**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identity of Recipient Cultivars**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identification of Items claimed as Confidential Business Information**

Items claimed as CBI as so indicated in the text as follows: [ CBI - Deleted ]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[ ]", as labeled as CBI.



**CBI - DELETED**

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-680XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 07, 1999

99-251-04n

**1. USDA Reference Number**

**2. Applicant Reference Number** 99-680XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

**4. Duration of Introduction**

Interstate Movement and Release Oct 07, 1999 - Oct 06, 2000

**5. Recipient** Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** glyphosate tolerant

Cultivar/ Variety Bobwhite, BW251

# CBI - DELETED

Monsanto Reference ID  
99-680XRAB

**designation of transformed line:** 33391, 33456, 33463

**Constructs:** PV-TXGT10

**genotype:**

**Gene of Interest**

- \* Promoter: CMoVa/I2 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

# CBI - DELETED

Monsanto Reference ID  
99-680XRAB

**designation of transformed line:** TA S1249, TA S1255, TA S1264, TA S1266, TA S1269, TA S1276, TA S1278, TA S1364, TA S1378, TA S1455, TA S1465, TA S1472, TA S1614, TA S1615, TA S2022, TA S2027

**Constructs:** PV-TXGT11

**genotype:**

**Gene of Interest**

- \* Promoter: CMP 3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' +2 -- [ CBI Deleted ]

**Gene of Interest**

- \* Promoter: CMoVa/I5 + leader1 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 3' -- [ CBI Deleted ]

# CBI - DELETED

Monsanto Reference ID  
99-680XRAB

**designation of transformed line:** 33512, 35710, 35845

**Constructs:** PV-TXGT12

**genotype:**

**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 -- [ CBI Deleted ]

**Gene of Interest**

- \* Promoter: CMP 3/I5 -- [ CBI Deleted ]
- \* Gene: CTP7-CP4 -- [ CBI Deleted ]
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

# CBI - DELETED

Monsanto Reference ID  
99-680XRAB

**designation of transformed line:** TA S537, TA S317, TA S342, TA S621, TA S635, TA S1081, TA S2520, TA S4490, TA S5070, TA S5450, TA S5451

**Constructs:** PV-TXGT13

**genotype:**

**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 3' -- [ CBI Deleted ]

# CBI - DELETED

Monsanto Reference ID  
99-680XRAB

**designation of transformed line:** TA S2744, TA S2747

**Constructs:** PV-TXGT15

**genotype:**

**Gene of Interest**

- \* Promoter: CMP 3/15 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 3' -- [ CBI Deleted ]



# CBI - DELETED

Monsanto Reference ID  
99-680XRAB

AZ (1)

AZ

\*

(b) (4)

Yuma County, AZ up to 4 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) Yuma County, AZ. Contact: (b) (6), (b) (7)(C), (b) (4)

MONSANTO

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63108

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID  
99-680XRAB

### 9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 07, 1999

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Monsanto Reference ID  
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Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 07, 1999

99-251-04n

- 1. USDA Reference Number \_\_\_\_\_
- 2. Applicant Reference Number 99-680XRAB
- 3. Applicant/Responsible Party

(b) (6), (b) (7)(C) [redacted]

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C) [redacted]

FAX

636/737-7085

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Email

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release Oct 07, 1999 - Oct 06, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate tolerant

Cultivar/ Variety Bobwhite, BW251

Monsanto Reference ID  
99-680XRAB

**designation of transformed line:** 33391, 33456, 33463

**Constructs:** PV-TXGT10

**genotype:**

**Gene of Interest**

- \* Promoter: CMoVa/I2 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
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Monsanto Reference ID  
99-680XRAB

**designation of transformed line:** TA S1249, TA S1255, TA S1264, TA S1266, TA S1269, TA S1276, T,  
S1278, TA S1364, TA S1378, TA S1455, TA S1465, TA S1472, TA  
S1614, TA S1615, TA S2022, TA S2027

**Constructs:** PV-TXGT11

**genotype:**

**Gene of Interest**

- \* Promoter: CMP 3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' +2 -- [ CBI Deleted ]

**Gene of Interest**

- \* Promoter: CMoVa/I5 + leader1 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 3' -- [ CBI Deleted ]

Monsanto Reference ID  
99-680XRAB

**designation of transformed line:** 33512, 35710, 35845

**Constructs:** PV-TXGT12

**genotype:**

**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 -- [ CBI Deleted ]

**Gene of Interest**

- \* Promoter: CMP 3/15 -- [ CBI Deleted ]
- \* Gene: CTP7-CP4 -- [ CBI Deleted ]
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI - DELETED

Monsanto Reference ID  
99-680XRAB

**designation of transformed line:** TA S537, TA S317, TA S342, TA S621, TA S635, TA S1081, TA S2520, TA S4490, TA S5070, TA S5450, TA S5451

**Constructs:** PV-TXGT13

**genotype:**

**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 3' -- [ CBI Deleted ]

Monsanto Reference ID  
99-680XRAB

**designation of transformed line:** TA S2744, TA S2747

**Constructs:** PV-TXGT15

**genotype:**

**Gene of Interest**

- \* Promoter: CMP 3/15 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
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**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: MI 3' -- [ CBI Deleted ]

Monsanto Reference ID  
99-680XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

Ship up to 600 pounds of wheat seed

**ORIGIN:** AZ MO **DESTINATION:** AZ MO

**Ship From:**

AZ

(b) (4) Yuma County, AZ

CONTACT: (b) (6), (b) (7)(C)  
Yuma County, AZ, (b) (6), (b) (7)(C)

MO

(b) (4) St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C)  
, St. Louis County, MO, (b) (6), (b) (7)(C)

**Ship To:**

AZ

(b) (4) Yuma County, AZ

CONTACT: (b) (6), (b) (7)(C), Yuma  
County, AZ, (b) (6), (b) (7)(C)

MO

(b) (4) St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C)  
St. Louis County, MO, (b) (6), (b) (7)(C) U.S.A., (b) (6), (b) (7)(C)

**Release Sites:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

CBI - DELETED

Monsanto Reference ID  
99-680XRAB

AZ (1)

AZ

\* (b) (4), Yuma County, AZ up to 4 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C)  
(b) (6), (b) (7)(C) Yuma County, AZ. Contact: (b) (6), (b) (7)(C)

MONSANTO

Food • Health • Hope



CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID  
99-680XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 07, 1999

file copy

Mr. G. John Caravetta, Associate Director  
Arizona Department of Agriculture  
1688 W. Adams  
Phoenix, AZ 85007

September 9, 1999

Dear Mr. Caravetta:

Enclosed is notification 99-251-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-04n	Applicant #:	99-680XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

September 9, 1999

Dear Mr. Brown:

Enclosed is notification 99-251-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-04n	Applicant #:	99-680XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. G. John Caravetta, Associate Director  
Arizona Department of Agriculture  
1688 W. Adams  
Phoenix, AZ 85007

September 9, 1999

Dear Mr. Caravetta:

Enclosed is notification 99-251-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number	99-251-04n	Applicant #:	99-680XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

B. Diane Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: G. John Caravetta

Signature: (b) (6), (b) (7)(C)

Date: 09/14/99

State: Arizona





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

September 9, 1999

Dear Mr. Brown:

Enclosed is notification 99-251-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-04n	Applicant #:	99-680XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

**(b) (6), (b) (7)(C)**

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

  y   State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: **(b) (6), (b) (7)(C)**

Date: 9-13-99

State: MO



September 16, 1999

(b) (6) [REDACTED]  
Monsanto Company  
700 Chesterfield Parkway N  
St. Louis, MO 63198

Dear (b) (6) [REDACTED]:

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 8, 1999.

Interstate movement and release  
Notification no. 99-251-04n (99-680XRAB)  
Regulated article - Wheat  
Destination(s) - Arizona, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official(s), and the Regional Program Manager(s), (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations  
Scientific Services  
Plant Protection and Quarantine

Enclosure

cc:

G. Caravetta, Arizona Dept. of Agric., Phoenix, AZ  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
D. DeWeese, PPQ, SCR, Jefferson City, MO  
R. Stoaks, PPQ, WR, Sacramento, CA  
File number 99-251-04n

OR120018\_BR\_012679

1999 Wheat Field Test Report  
USDA # 99-251-04n Monsanto # 99-680XRAB

(b) (6), (b) (7)(C)

April 16, 2001

Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
(b) (4)	Yuma	AZ

Yuma, AZ

Planting Date: November 2, 1999

Harvest /Destruct Date: April 20, 2000

Vector Constructs/Line Numbers Planted (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

0.

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Disposition of the seed: (b) (4)

1999 Wheat Field Test Report  
USDA # 99-251-04n Monsanto # 99-680XRAB

(b) (4), (b) (6), (b) (7)(C)

October 3, 2000

Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
(b) (4)	Yuma	AZ

Yuma, AZ

Planting Date: November 2, 1999

Harvest Date: April 20, 2000

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Disposition of the seed: (b) (4)



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Monsanto Reference ID  
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Permit Unit  
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4700 River Rd.  
Riverdale, MD 20737

Sep 07, 1999

99-251-05n

- 1. USDA Reference Number
- 2. Applicant Reference Number
- 3. Applicant/Responsible Party

99-681XRAB

(b) (6), (b) (7)(C)

Monsanto Company  
700 Cheserfield Parkway North  
St. Louis, MO

Phone (b) (6), (b) (7)(C)  
 FAX 636/737-7085  
 EMail (b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release Oct 07, 1999 - Oct 06, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT  
 Phenotype: glycosate tolerant  
 Cultivar/Variety Bobwhite, BW251, ACBarrie

# CONFIDENTIAL

Monsanto Reference ID  
99-681XRAB

**designation of transformed line:** 25397

**Constructs:** PV-TXGT05

**genotype:**

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [REDACTED] (b) (4) ] - CBI *CBI*
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: CMoVa/I5 -- [REDACTED] (b) (4) ] - CBI *CBI*
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



*CONFIDENTIAL*

Monsanto Reference ID  
99-681XRAB

AZ (1)

AZ

\* [REDACTED] (b) (4) Yuma County, AZ up to 2 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

[REDACTED], Yuma County, AZ. Contact: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

MONSANTO



Food · Health · Hope

**CONFIDENTIAL**

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-681XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company  
Sep 07, 1999

## CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, And Expressed Traits**

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **Identity And Characteristics Of Donor Organism**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identity of Recipient Cultivars**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identification of Items claimed as Confidential Business Information**

Items claimed as CBI as so indicated in the text as follows: [ CBI - Deleted ]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[ ]", as labeled as CBI.



CBI - DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63108  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-681XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 07, 1999

99-251-05n

**1. USDA Reference Number**

**2. Applicant Reference Number** 99-681XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

**4. Duration of Introduction**

Interstate Movement and Release Oct 07, 1999 - Oct 06, 2000

**5. Recipient** Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** glycosate tolerant

Cultivar/Variety Bobwhite, BW251, ACBarrie

# CBI - DELETED

Monsanto Reference ID  
99-681XRAB

designation of transformed line: 25397

**Constructs:** PV-TXGT05

**genotype:**

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: CMoVa/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID  
99-681XRAB

- 7. **Mode of Transformation**      Particle Bombardment
- 8. **Introduction**                      Interstate Movement and Release

Ship up to 1050 pounds of wheat seed before and after harvest

<b>ORIGIN:</b>		<b>DESTINATION:</b>	
AZ	MO	AZ	MO

**Ship From:**

AZ

\* (b) (4), Yuma County, AZ

CONTACT: (b) (6), (b) (7)(C), (b) (4), Yuma,  
Yuma County, AZ, (b) (6), (b) (7)(C), (b) (4)

MO

\*] (b) (4), St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)  
(b) (6), (b) (7)(C), (b) (4) St. Louis County, MO,

**Ship To:**

AZ

\* (b) (4) Yuma County, AZ

CONTACT: (b) (6), (b) (7)(C), (b) (4), Yuma  
County, AZ, (b) (6), (b) (7)(C), (b) (4)

MO

\* (b) (4), MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4),  
St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

**Release Sites:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

# CBI - DELETED

Monsanto Reference ID  
99-681XRAB

AZ (1)

AZ

\*

(b) (4)

, Yuma County, AZ up to 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) Yuma County, AZ. Contact: (b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food · Health · Hope



CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID  
99-681XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 07, 1999



CBI - DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-681XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 07, 1999

99-251-05n

1. **USDA Reference Number**
2. **Applicant Reference Number**
3. **Applicant/Responsible Party**

99-681XRAB

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. **Duration of Introduction**

Interstate Movement and Release · Oct 07, 1999 - Oct 06, 2000

5. **Recipient** Wheat, Triticum aestivum

6. **Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** glycosate tolerant

Cultivar/Variety Bobwhite, BW251, ACBarrie

Monsanto Reference ID  
99-681XRAB

**designation of transformed line:** 25397

**Constructs:** PV-TXGT05

**genotype:**

**Gene of Interest**

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Monsanto Reference ID  
99-681XRAB

7. Mode of Transformation Particle Bombardment

8. Introduction Interstate Movement and Release

Ship up to 1050 pounds of wheat seed before and after harvest

ORIGIN: AZ MO DESTINATION: AZ MO

Ship From:

AZ

\* (b) (4) Yuma County, AZ

CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED]  
Yuma County, AZ, (b) (6), (b) (7)(C), (b) (4) [REDACTED]

MO

\* (b) (4) St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED]  
[REDACTED], St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4) [REDACTED]

Ship To:

AZ

\* (b) (4) Yuma County, AZ

CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED], Yuma  
County, AZ, (b) (6), (b) (7)(C), (b) (4) [REDACTED]

MO

\* (b) (4) St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED]  
St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4) [REDACTED] U.S.A., (b) (6), (b) (7)(C), (b) (4) [REDACTED]

Release Sites:

NUMBER OF STATES/TERRITORIES AND SITES:

CBI - DELETED

Monsanto Reference ID  
99-681XRAB

AZ (1)

AZ

\*

(b) (4)

Yuma County, AZ up to 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)  
Yuma County, AZ. Contact: (b) (6), (b) (7)(C), (b) (4)



CBI - DELETED

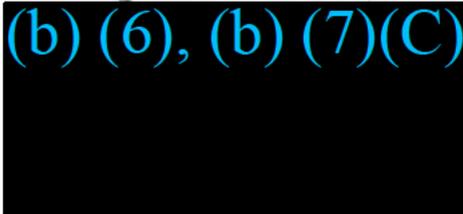
MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-681XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

Sep 07, 1999

file copy

Mr. G. John Caravetta, Associate Director  
Arizona Department of Agriculture  
1688 W. Adams  
Phoenix, AZ 85007

September 9, 1999

Dear Mr. Caravetta:

Enclosed is notification 99-251-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-05n	Applicant #:	99-681XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

September 9, 1999

Dear Mr. Brown:

Enclosed is notification 99-251-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-05n	Applicant #:	99-681XRAB
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Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. G. John Caravetta, Associate Director  
Arizona Department of Agriculture  
1688 W. Adams  
Phoenix, AZ 85007

September 9, 1999

Dear Mr. Caravetta:

Enclosed is notification 99-251-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-05n	Applicant #:	99-681XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

**(b) (6), (b) (7)(C)**

E. Diane Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: G. John Caravetta

Signature: **(b) (6), (b) (7)(C)**

Date: 09/14/99

State: Arizona





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

September 9, 1999

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

Dear Mr. Brown:

Enclosed is notification 99-251-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-251-05n	Applicant #:	99-681XRAB
Received:	September 8, 1999	Effective:	October 8, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

**(b) (6), (b) (7)(C)**

E. Diane Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: **(b) (6), (b) (7)(C)**

Date: 9-13-99

State: MO



September 16, 1999

(b) (6), (b) (7)(C) [REDACTED]  
Monsanto Company  
700 Chesterfield Parkway N  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C) [REDACTED]:

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 8, 1999.

Interstate movement and release  
Notification no. 99-251-05n (99-681XRAB)  
Regulated article - Wheat  
Destination(s) - Arizona, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Official(s), and the Regional Program Manager(s), (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations  
Scientific Services  
Plant Protection and Quarantine

Enclosure

cc:  
G. Caravetta, Arizona Dept. of Agric., Phoenix, AZ  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
D. DeWeese, PPQ, SCR, Jefferson City, MO  
R. Stoaks, PPQ, WR, Sacramento, CA  
File number 99-251-05n

OR120018\_BR\_012705

1999 Wheat Field Test Report  
USDA # 99-251-05n Monsanto # 99-681XRAB

(b) (6), (b) (7)(C)

April 16, 2001

Monsanto Company

Location

(b) (4)

County

Yuma

State

AZ (NOT PLANTED)



MONSANTO

Food • Health • Hope



**CONFIDENTIAL**

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
http://www.monsanto.com

Monsanto Reference ID  
99-713XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 14, 1999

99 - 259 - 03n

**1. USDA Reference Number**

**2. Applicant Reference Number**

99-713XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

**4. Duration of Introduction**

Interstate Movement and Release

Oct 14, 1999 - Oct 13, 2000

**5. Recipient**

Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** glyphosate tolerant

Cultivar/Variety Backcross progeny derived from transgenic Bobwhite and BZ991-408HW, BZ992-588, Express, Impervo, West Bred 926, West Bred 936, Brooks

# CONFIDENTIAL

Monsanto Reference ID  
99-713XRAB

**designation of transformed line:** 25397

**Constructs:** PV-TXGT05

**genotype:**

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ (b) (4) ] - CBI CBI
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: CMoVa/I5 -- [ (b) (4) ] - CBI CBI
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



*CONFIDENTIAL*

Monsanto Reference ID  
99-713XRAB

AZ (1)

AZ

\* [REDACTED] (b) (4), Yuma County, AZ 1 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

[REDACTED] Yuma County, AZ. Contact: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

RECEIVED

MONSANTO



Food • Health • Hope

**CONFIDENTIAL**

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-713XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company  
Sep 14, 1999

## CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

### **Legal Background**

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

### **Gene Description**

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, And Expressed Traits**

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents *for* the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **Identity And Characteristics Of Donor Organism**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identity of Recipient Cultivars**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identification of Items claimed as Confidential Business Information**

Items claimed as CBI as so indicated in the text as follows: [ CBI - Deleted ]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[ ]", as labeled as CBI.



CBI - DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63108  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-713XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 14, 1999

99-259-03n

**1. USDA Reference Number**

**2. Applicant Reference Number** 99-713XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

**4. Duration of Introduction**

Interstate Movement and Release Oct 14, 1999 - Oct 13, 2000

**5. Recipient** Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** glyphosate tolerant

Cultivar/Variety Backcross progeny derived from transgenic Bobwhite and BZ991-408HW, BZ992-588, Express, Impervo, West Bred 926, West Bred 936, Brooks

# CBI - DELETED

Monsanto Reference ID  
99-713XRAB

**designation of transformed line:** 25397

**Constructs:** PV-TXGT05

**genotype:**

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

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# CBI - DELETED

Monsanto Reference ID  
99-713XRAB

- 7. **Mode of Transformation** Particle Bombardment
- 8. **Introduction** Interstate Movement and Release

Ship up to 60 pounds of wheat seed before and after harvest

**ORIGIN:** AZ MO **DESTINATION:** AZ MO

**Ship From:**

AZ

\* (b) (4) Yuma County, AZ (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
Yuma County, AZ, (b) (6), (b) (7)(C)

MO

\*] (b) (4) St. Louis County, MO 63198

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

**Ship To:**

AZ

\*] (b) (4) , Yuma County, AZ 85366

CONTACT: [REDACTED] (b) [REDACTED]  
Yuma County, AZ, (b) (6),

MO

\* [REDACTED] (b) (4) , St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

**Release Sites:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

# CBI - DELETED

Monsanto Reference ID  
99-713XRAB

AZ (1)

AZ

\* (b) (4) Yuma County, AZ 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) Yuma County, AZ. Contact: (b) (6), (b) (7)(C), (b) (4)



CBI - DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63108  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-713XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company  
Sep 14, 1999

MONSANTO

Food · Health · Hope



CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

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Monsanto Reference ID  
99-713XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 14, 1999

99-259-03n

**1. USDA Reference Number**

**2. Applicant Reference Number** 99-713XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EEmail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

**4. Duration of Introduction**

Interstate Movement and Release Oct 14, 1999 - Oct 13, 2000

**5. Recipient** Wheat, Triticum aestivum

**6. Regulated Article**

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**Phenotype:** glyphosate tolerant

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Monsanto Reference ID  
99-713XRAB

designation of transformed line: 25397

Constructs: PV-TXGT05

genotype:

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CBI - DELETED

Monsanto Reference ID  
99-713XRAB

AZ (1)

AZ

\* (b) (4), Yuma County, AZ 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)  
(b) (6), (b) (7)(C), (b) (4) Yuma County, AZ. Contact: (b) (6), (b) (7)(C), (b) (4)



CBI - DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-713XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 14, 1999

file copy

Mr. G. John Caravetta, Associate Director  
Arizona Department of Agriculture  
1688 W. Adams  
Phoenix, AZ 85007

September 17, 1999

Dear Mr. Caravetta:

Enclosed is notification 99-259-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-259-03n	Applicant #:	99-713XRAB
Received:	September 16, 1999	Effective:	October 16, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

OR120018\_BR\_012726

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

September 17, 1999

Dear Mr. Brown:

Enclosed is notification 99-259-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-259-03n	Applicant #:	99-713XRAB
Received:	September 16, 1999	Effective:	October 16, 1999
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Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

**FAXED**

Mr. G. John Caravetta, Associate Director  
Arizona Department of Agriculture  
1688 W. Adams  
Phoenix, AZ 85007

September 17, 1999

Dear Mr. Caravetta:

Enclosed is notification 99-259-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-259-03n	Applicant #:	99-713XRAB
Received:	September 16, 1999	Effective:	October 16, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

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It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

**(b) (6), (b) (7)(C)**

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: G. John Caravetta

Signature

**(b) (6), (b) (7)(C)**

Date: 09/22/99

State: Arizona





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

September 17, 1999

Dear Mr. Brown:

Enclosed is notification 99-259-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-259-03n	Applicant #:	99-713XRAB
Received:	September 16, 1999	Effective:	October 16, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

**(b) (6), (b) (7)(C)**

Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

  X   State concurs with APHIS determination.

       State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: **(b) (6), (b) (7)(C)**

Date: 9-22-99

State: MO



October 12, 1999

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Pkwy N  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C):

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 16, 1999.

Interstate movement and Release  
Notification no. 99-259-03n (99-713XRAB)  
Regulated article - Wheat  
Destinations - Arizona, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations  
Scientific Services  
Plant Protection and Quarantine

Enclosure

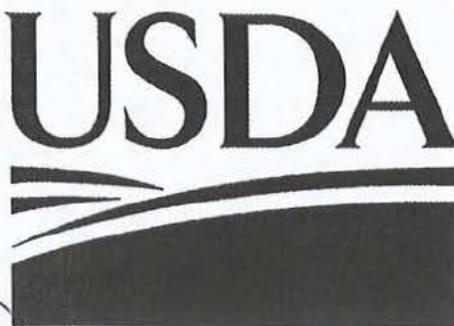
cc:

J. Caravetta, Arizona Dept. of Agric., Phoenix, AZ  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
D. DeWeese, PPQ, SCR, Jefferson City, MO  
R. Stoaks, PPQ, WR, Sacramento, CA  
File number 99-259-03n

OR120018\_BR\_012730

99-259-03N

Reviewed  
by Dr. Karen  
Hobanson



**ANIMAL AND PLANT HEALTH INSPECTION SERVICE**  
USDA APHIS PPQ  
Inspection Station  
Honolulu International Airport  
300 Rodgers Blvd. #57  
Honolulu, HI 96819-1897

**FACSIMILE SHEET**

TO <b>RALPH STOAKS</b>		OFFICE <b>USDA APHIS PPQ</b>	CITY AND STATE <b>SACRAMENTO CA</b>
OFFICE TELEPHONE NO <b>916-857-6105</b>	FAX TELEPHONE NO <b>916-857-6156</b>	DATE <b>SEPT 10 1999</b>	TIME

SUBJECT  
**RE. YOUR AUG 25 MEMO "PRIORITY BIOTECH INSPECTIONS"**

REMARKS

RALPH:

As requested in your memo of August 25 I attach the two requested reports regarding 99-139-02n and 98-259-03n. Carol Okada (HI State) and I visited the Waimanalo fields yesterday, accompanied by Hubert Olipares (UH). Neither Dr. Stiles nor Dr. Manshardt were able to attend; the former having to appear (from what I understand) a legislative meeting, the latter having classroom teaching duties. This was unfortunate, but because of the time constraints your memo imposed together with my having to attend Federal jury duty starting next week Tuesday (for an undetermined time period), it was felt that the visit should be done as soon as possible. I hope that the attached will provide the needed information.

Bill Hoe

- ACTION
- APPROVAL
- AS REQUESTED
- FOR COMMENT
- FOR INFORMATION

FROM <b>William J. Hoe, PhD Area Identifier - Botany</b>		OFFICE <b>USDA APHIS PPQ</b>	CITY AND STATE <b>Honolulu, Hawaii</b>
OFFICE TELEPHONE NO. <b>808-861-8494</b>	FAX TELEPHONE NO <b>808-861-8500</b>	DATE <b>Sept 10, 1999</b>	TIME

NUMBER OF PAGES INCLUDING TRANSMITTAL SHEET **35 (will be mailed)**

*2, this transmission.*



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection  
Service

Plant Protection  
and Quarantine

USDA APHIS PPQ  
Inspection Station  
Honolulu International Airport  
300 Rodgers Blvd. #57  
Honolulu, HI 96819-1897

Subject: STOAKS MEMO DATED AUGUST 25, 1999

Date: SEPTEMBER 10, 1999

To: DR. RALPH STOAKS

ATTACHMENT SHEET TO MY FAX OF SEP. 10, TO ACCOMPANY DOCUMENTS BEING MAILED.

Materials supplied by principle investigators, neither of whom was able to accompany Carol Okada and me to the Waimanalo planting site.

- I. 99-139-02n (b) (6), (b) (7)(C)  
4pp total, including statement from (b) (6), (b) (7)(C) indicating that the planting had not yet occurred. We visited the site; it is a fallow field. No performance standard since no planting has yet occurred.
- II. 98-259-03n (b) (6), (b) (7)(C)  
24pp total. Project close to termination. Perhaps due to past problems with record keeping, etc. (b) (6), (b) (7)(C) now uses an observation sheet to be filled out at the time of each visit. These have been provided to us. Performance standard attached.
- III. Memo to (b) (6), (b) (7)(C) dated September 9, from (b) (6), (b) (7)(C), indicating status of the two fields. 2 pp. For your information.
- IV. Copy of article from *The New York Times* for information.

Bill Hoe  
Sept 10, 1999



1706

Mr. Myron Isherwood Jr., Manager  
Plant Quarantine Branch  
Hawaii Department of Agriculture  
701 Ilalo Street  
Honolulu, HI 96813

May 25, 1999

Dear Mr. Isherwood Jr.:

Enclosed is notification 99-139-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-139-02n	Applicant #:	CA-1
Received:	May 19, 1999	Effective:	June 18, 1999
Institution:	U of Hawaii	Recipient:	
Interstate destination:			
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

Permits Branch  
Biotechnology Permits  
Biotechnology, Biologics, and Environmental Protection  
4700 River Road  
Riverdale, MD 20737-1228  
Fax: 301-734-8910

1. Reference Number: 99-139-02n
2. Applicant Reference Number: CA-1
3. Applicant/Responsible party:

(b) (6), (b) (7)(C), (b) (4)  
(b) (6), (b) (7)(C), (b) (4)  
(b) (6), (b) (7)(C), (b) (4)

Phone: (b) (6), (b) (7)(C), (b) (4)  
Fax: (b) (6), (b) (7)(C), (b) (4)  
Email: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4), Hawaii  
Phone: (b) (6), (b) (7)(C), (b) (4)  
Fax: (b) (6), (b) (7)(C), (b) (4)  
Email: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)  
(7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4), Hawaii  
Phone: (b) (6), (b) (7)(C), (b) (4)  
Fax: (b) (6), (b) (7)(C), (b) (4)  
Email: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4), Hawaii  
Phone: (b) (6), (b) (7)(C), (b) (4)  
Fax: (b) (6), (b) (7)(C), (b) (4)  
Email: (b) (6), (b) (7)(C), (b) (4)

4. Duration of Introduction:

Release: July 1999 - December 2004

5. Recipient: Coffee, Coffea arabica

6. Regulated Article:

a) ACC synthase cDNA in antisense orientation:

1) Category: Product quality (PQ)  
Phenotype: Reduced ethylene production  
Construct: pKRC-ACS-A  
Promoter: 35S 5' from CaMV  
Gene: ACC synthase from ripening coffee fruits as cDNA in  
antisense orientation  
Terminator: NOS 3' from Agrobacterium tumifaciens  
Selectable marker:  
Promoter: NOS 5' from Agrobacterium tumifaciens  
Gene: Neomycin phosphotransferase II (NPT II)  
from E. coli TN5  
Terminator: NOS 3' from Agrobacterium tumifaciens

7. Mode of Transformation: Coffee plants were transformed using Agrobacterium tumifaciens

8. Introduction:

Release:

NUMBER OF STATES/TERRITORIES AND SITES: HI (1)

(b) (4), HI  
(City and County of Honolulu)

9. Certification: I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Name Typed: (b) (4) (b) (4) (b) (4)

Permits Branch  
Biotechnology Permits  
Biotechnology, Biologics, and Environmental Protection  
4700 River Road  
Riverdale, MD 20737-1228

# FAX

**TO:** Hubert B. Olipares  
Biological Safety Officer  
956-3205

**FROM:** [REDACTED] (b) (6), (b) (7)(C), (b) (4)

**RE:** Field trials of transgenic coffee

This is to inform you that we have not, as yet initiated planting of transgenic coffee plants in [REDACTED] (b) (4). We anticipate the initial plantings to within the next 60 days. You will be notified at least one week prior to any plantings.

If you have any questions please feel free to contact me.

[REDACTED] (b) (6), (b) (7)(C), (b) (4)



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MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63108  
PHONE (314) 694-1000  
http://www.monsanto.com

Monsanto Reference ID  
99-714XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 14, 1999

99-259-04n

**1. USDA Reference Number**

**2. Applicant Reference Number** 99-714XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

**4. Duration of Introduction**

Interstate Movement and Release Oct 14, 1999 - Oct 13, 2000

**5. Recipient** Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** glyphosate tolerant

Cultivar/Variety Backcrosses progeny derived from transgenic Bobwhite and BZ991-408HW, BZ992-588, Express, Impervo, West Bred 926, West Bred 936, Brooks

# CONFIDENTIAL

Monsanto Reference ID  
99-714XRAB

**designation of transformed line:** 33391, 33456, 33463

**Constructs:** PV-TXGT10

**genotype:**

**Gene of Interest**

\* Promoter: CMoVa/I2 -- [REDACTED] (b) (4) ] - CBI

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

\* Promoter: CMP3/I5 -- [REDACTED] (b) (4) ] - CBI

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

# CONFIDENTIAL

Monsanto Reference ID  
99-714XRAB

**designation of transformed line:** 33512

**Constructs:** PV-TXGT12

**genotype:**

**Gene of Interest**

\* Promoter: MP4 -- [REDACTED] (b) (4) ] - CBI

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: M1 -- [REDACTED] (b) (4) ] - CBI

**Gene of Interest**

\* Promoter: CMP 3/15 -- [REDACTED] (b) (4) ] - CBI

\* Gene: CTP7-CP4 -- [REDACTED] (b) (4) ] - CBI

\* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



# CONFIDENTIAL

Monsanto Reference ID  
99-714XRAB

AZ (1)

AZ

\* [REDACTED] (b) (4), Yuma County, AZ 1 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

[REDACTED] Yuma County, AZ. Contact: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

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ST. LOUIS, MISSOURI 63108  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-714XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company  
Sep 14, 1999

## CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, And Expressed Traits**

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents *for* the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **Identity And Characteristics Of Donor Organism**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identity of Recipient Cultivars**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identification of Items claimed as Confidential Business Information**

Items claimed as CBI as so indicated in the text as follows: [ CBI - Deleted ]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, “[ ]”, as labeled as CBI.



CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63108  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-714XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 14, 1999

99-259-04n

1. **USDA Reference Number**
2. **Applicant Reference Number**
3. **Applicant/Responsible Party**

99-714XRAB

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. **Duration of Introduction**

Interstate Movement and Release      Oct 14, 1999 - Oct 13, 2000

5. **Recipient**      Wheat, Triticum aestivum

6. **Regulated Article**

**Phenotypic Category:**      HT

**Phenotype:**      glyphosate tolerant

Cultivar/Variety Backcrosses progeny derived from transgenic Bobwhite and BZ991-408HW, BZ992-588, Express, Impervo, West Bred 926, West Bred 936, Brooks

# CBI - DELETED

Monsanto Reference ID  
99-714XRAB

**designation of transformed line:** 33391, 33456, 33463

**Constructs:** PV-TXGT10

**genotype:**

**Gene of Interest**

- \* Promoter: CMoVa/I2 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

# CBI - DELETED

Monsanto Reference ID  
99-714XRAB

**designation of transformed line:** 33512

**Constructs:** PV-TXGT12

**genotype:**

**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 -- [ CBI Deleted ]

**Gene of Interest**

- \* Promoter: CMP 3/15 -- [ CBI Deleted ]
- \* Gene: CTP7-CP4 -- [ CBI Deleted ]
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.



# CBI - DELETED

Monsanto Reference ID  
99-714XRAB

AZ (1)

AZ

\* (b) (4), Yuma County, AZ 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) Yuma County, AZ. Contact: (b) (6), (b) (7)(C), (b) (4)

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID  
99-714XRAB

### 9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 14, 1999

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CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

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Monsanto Reference ID  
99-714XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 14, 1999

99-259-04n

**1. USDA Reference Number**

**2. Applicant Reference Number** 99-714XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

**4. Duration of Introduction**

Interstate Movement and Release Oct 14, 1999 - Oct 13, 2000

**5. Recipient** Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** glyphosate tolerant

Cultivar/Variety Backcrosses progeny derived from transgenic Bobwhite and BZ991-408HW, BZ992-588, Express, Impervo, West Bred 926, West Bred 936, Brooks

Monsanto Reference ID  
99-714XRAB

**designation of transformed line:** 33391, 33456, 33463

**Constructs:** PV-TXGT10

**genotype:**

**Gene of Interest**

- \* Promoter: CMoVa/I2 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI - DELETED

Monsanto Reference ID  
99-714XRAB

**designation of transformed line:** 33512

**Constructs:** PV-TXGT12

**genotype:**

**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 -- [ CBI Deleted ]

**Gene of Interest**

- \* Promoter: CMP 3/15 -- [ CBI Deleted ]
- \* Gene: CTP7-CP4 -- [ CBI Deleted ]
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID  
99-714XRAB

- 7. **Mode of Transformation**    Disarmed Agrobacterium tumefaciens
- 8. **Introduction**                Interstate Movement and Release

Ship up to 60 pounds of wheat seed before and after harvest.

<b>ORIGIN:</b>		<b>DESTINATION:</b>	
AZ	MO	AZ	MO

**Ship From:**

AZ

\* [REDACTED] (b) (4), Yuma County, AZ (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
Yuma County, AZ, (b) (6), (b) (7)(C)

MO

[REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

**Ship To:**

AZ

[REDACTED] (b) (6), [REDACTED] (b) (6), Yuma County, AZ (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
Yuma County, AZ, (b) (6), (b) (7)(C)

MO

\* [REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

**Release Sites:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

CBI - DELETED

Monsanto Reference ID  
99-714XRAB

AZ (1)

AZ

\* [REDACTED] (b) (4), Yuma County, AZ 1 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

[REDACTED] Yuma County, AZ. Contact [REDACTED] (b) (6), (b) (7)(C), (b) (4)



CBI - DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-714XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (7)(C), (b) (6)

Monsanto Company

Sep 14, 1999

file copy

Mr. G. John Caravetta, Associate Director  
Arizona Department of Agriculture  
1688 W. Adams  
Phoenix, AZ 85007

September 17, 1999

Dear Mr. Caravetta:

Enclosed is notification 99-259-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-259-04n	Applicant #:	99-714XRAB
Received:	September 16, 1999	Effective:	October 16, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

September 17, 1999

Dear Mr. Brown:

Enclosed is notification 99-259-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-259-04n	Applicant #:	99-714XRAB
Received:	September 16, 1999	Effective:	October 16, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

**FAXED**

Mr. G. John Caravetta, Associate Director  
Arizona Department of Agriculture  
1688 W. Adams  
Phoenix, AZ 85007

September 17, 1999

Dear Mr. Caravetta:

Enclosed is notification 99-259-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-259-04n	Applicant #:	99-714XRAB
Received:	September 16, 1999	Effective:	October 16, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

**(b) (7)(C), (b) (6)**

E. Dianne Halmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: G. John Caravetta

Signature: **(b) (7)(C), (b) (6)**

Date: 09/22/99

State: Arizona





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

September 17, 1999

Dear Mr. Brown:

Enclosed is notification 99-259-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-259-04n	Applicant #:	99-714XRAB
Received:	September 16, 1999	Effective:	October 16, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ MO		
Release destination:	AZ		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (7)(C), (b) (6)

E. Diane Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (7)(C), (b) (6)

Date: 9-22-99

State: MO



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

October 12, 1999

(b) (7)(C), (b) (7)(D) [REDACTED]  
Monsanto Company  
700 Chesterfield Pkwy N  
St. Louis, MO 63198

Dear (b) (7)(C), (b) (7)(D) [REDACTED]:

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 16, 1999.

Interstate movement and Release  
Notification no. 99-259-04n (99-714XRAB)  
Regulated article - Wheat  
Destinations - Arizona, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations  
Scientific Services  
Plant Protection and Quarantine

Enclosure

cc:

J. Caravetta, Arizona Dept. of Agric., Phoenix, AZ  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
D. DeWeese, PPQ, SCR, Jefferson City, MO  
R. Stoaks, PPQ, WR, Sacramento, CA

File number 99-259-04n

OR120018\_BR\_012763

1999 Wheat Field Test Report  
USDA # 99-259-04n Monsanto # 99-714XRAB

(b) (7)(C), (b) (6)  
April 16, 2001

Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
(b) (4)	Yuma	AZ

Yuma, AZ

Planting Date: January 15, 2000

Harvest Date: May 2, 2000

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Field Monitoring for Plant Stand: (b) (4)

Disposition of the seed: (b) (4)

1999 Wheat Field Test Report  
USDA # 99-259-04n Monsanto # 99-714XRAB

(b) (7)(C), (b) (6)

October 4, 2000

Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
(b) (4)	Yuma	AZ

Yuma, AZ

Planting Date: January 15, 2000

Harvest Date: May 2, 2000

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Field Monitoring for Plant Stand: (b) (4)

Disposition of the seed: (b) (4)



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**CONFIDENTIAL**

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
http://www.monsanto.com

Monsanto Reference ID  
99-726XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 21, 1999

99-266-02n

**1. USDA Reference Number**

**2. Applicant Reference Number** 99-726XRAB

**3. Applicant/Responsible Party**

(b) (7)(C), (b) (6)

Phone

(b) (7)(C), (b) (6)

FAX

636/737-7085

EMail

(b) (7)(C), (b) (6)@monsanto.com

Monsanto Company  
700 Cheserfield Parkway North  
St. Louis, MO

**4. Duration of Introduction**

Interstate Movement and Release Oct 21, 1999 - Oct 20, 2000

**5. Recipient** Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT  
**Phenotype:** Glyphosate Tolerant  
Cultivar/ Variety Bobwhite, BW251, AC Barrie

# CONFIDENTIAL

Monsanto Reference ID  
99-726XRAB

**designation of transformed line:** 33391, 33456, 33463

**Constructs:** PV-TXGT10

**genotype:**

**Gene of Interest**

\* Promoter: CMoVa/I2 -- [ (b) (4) ] - CBI CBI

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

\* Promoter: CMP3/I5 -- [ (b) (4) ] - CBI CBI

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

# CONFIDENTIAL

Monsanto Reference ID  
99-726XRAB

designation of transformed line: 33512

**Constructs:** PV-TXGT12

**genotype:**

**Gene of Interest**

\* Promoter: MP4 -- [REDACTED] (b) (4) ] - CBI

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: M1 -- [REDACTED] (b) (4) ] - CBI

**Gene of Interest**

\* Promoter: CMP 3/15 -- [REDACTED] (b) (4) ] - CBI

\* Gene: CTP7-CP4 -- [REDACTED] (b) (4) ] - CBI

\* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

# CONFIDENTIAL

Monsanto Reference ID  
99-726XRAB

7. **Mode of Transformation** Disarmed Agrobacterium tumefaciens  
8. **Introduction** Interstate Movement and Release

Ship up to 9000 pounds of wheat seed before and after harvest

<b>ORIGIN:</b>		<b>DESTINATION:</b>	
CA	HI	CA	HI
MO		MO	

**Ship From:**

CA

(b) (4), Kern County, CA (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) Kern County, CA

(b) (4), Imperial County, CA

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
Yuma County, AZ, (b) (4), (b) (6), (b) (7)(C)

HI

(b) (4), Honolulu County, HI  
(b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) Honolulu County, HI

MO

(b) (4), St. Louis County, MO (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), (b) (6), (b) (7)(C) St. Louis County, MO

**Ship To:**

CA

# CONFIDENTIAL

Monsanto Reference ID  
99-726XRAB

(b) (4), Kern County, CA (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
Kern County, CA, (b) (4), (b) (6), (b) (7)(C) USA

\* (b) (4), Imperial County, CA

CONTACT: (b) (4), (b) (6), (b) (7)(C), Yuma  
County, AZ, (b) (4), (b) (6), (b) (7)(C)

## HI

(b) (4), Honolulu County, HI  
(b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
(b) (4), Honolulu County, HI, (b) (4), (b) (6), (b) (7)(C)

## MO

(b) (4), St. Louis County, MO (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C)  
St. Louis County, MO, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

## Release Sites:

### NUMBER OF STATES/TERRITORIES AND SITES:

CA (2) HI (1)

#### CA

\* (b) (4), Kern County, CA 1 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4) Kern County, CA. Contact: (b) (4), (b) (6), (b) (7)(C).

\* (b) (4), Imperial County, CA 2 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)  
(b) (4) Yuma County, AZ. Contact: (b) (4), (b) (6), (b) (7)(C)

# CONFIDENTIAL

Monsanto Reference ID  
99-726XRAB

*HI*

\* [REDACTED] (b) (4) Honolulu County, HI 5 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (4), (b) (6), (b) (7)(C)  
[REDACTED] Honolulu County, HI. Contact: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

MONSANTO

Food • Health • Hope



**CONFIDENTIAL**

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-726XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

**(b) (6), (b) (7)(C)**

Monsanto Company  
Sep 21, 1999

## CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, And Expressed Traits**

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents *for* the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **Identity And Characteristics Of Donor Organism**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identity of Recipient Cultivars**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identification of Items claimed as Confidential Business Information**

Items claimed as CBI as so indicated in the text as follows: [ CBI - Deleted ]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, "[ ]", as labeled as CBI.



CBI - DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
http://www.monsanto.com

Monsanto Reference ID  
99-726XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 21, 1999

99-266-02n

- 1. USDA Reference Number
- 2. Applicant Reference Number
- 3. Applicant/Responsible Party

99-726XRAB

[REDACTED]

Phone

(b) (6), (b) (7)(C)

[REDACTED]

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North  
St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release      Oct 21, 1999 - Oct 20, 2000

5. Recipient      Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:      HT

Phenotype:      Glyphosate Tolerant

Cultivar/ Variety Bobwhite, BW251, AC Barrie

# CBI - DELETED

Monsanto Reference ID  
99-726XRAB

**designation of transformed line:** 33391, 33456, 33463

**Constructs:** PV-TXGT10

**genotype:**

**Gene of Interest**

- \* Promoter: CMoVa/I2 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

# CBI - DELETED

Monsanto Reference ID  
99-726XRAB

**designation of transformed line:** 33512

**Constructs:** PV-TXGT12

**genotype:**

**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 -- [ CBI Deleted ]

**Gene of Interest**

- \* Promoter: CMP 3/I5 -- [ CBI Deleted ]
- \* Gene: CTP7-CP4 -- [ CBI Deleted ]
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

# CBI - DELETED

Monsanto Reference ID  
99-726XRAB

**7. Mode of Transformation** Disarmed Agrobacterium tumefaciens

**8. Introduction** Interstate Movement and Release

Ship up to 9000 pounds of wheat seed before and after harvest

<b>ORIGIN:</b>			<b>DESTINATION:</b>		
CA		HI	CA		HI
MO			MO		

**Ship From:**

CA

(b) (4), Kern County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)  
(b) (4), Kern County, CA, (b) (6), (b) (7)(C)

(b) (4) Imperial County, CA

CONTACT: (b) (6), (b) (7)(C), (b) (4)  
Yuma County, AZ, (b) (6), (b) (7)(C), (b) (4)

HI

(b) (4), Honolulu County, HI  
(b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)  
(b) (4), Honolulu County, HI, (b) (6), (b) (7)(C), (b) (4)

MO

(b) (4), St. Louis County, MO (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4)  
(b) (4), St. Louis County, MO, (b) (6), (b) (7)(C), (b) (4)

**Ship To:**

CA

# CBI - DELETED

Monsanto Reference ID  
99-726XRAB

\* [REDACTED] (b) (4), Kern County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
Kern County, CA (b) (6), (b) (7)(C) USA

\* [REDACTED] (b) (4), Imperial County, CA

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4), Yuma  
County, AZ, (b) (6), (b) (7)(C), (b) (4)

## HI

\* [REDACTED] (b) (4), Honolulu County, HI

(b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Honolulu County, HI, (b) (6), (b) (7)(C), (b) (4)

## MO

\* [REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
St. Louis County, MO, (b) (6), (b) (7)(C) U.S.A., (b) (6), (b) (7)(C), (b) (4)

## Release Sites:

### NUMBER OF STATES/TERRITORIES AND SITES:

CA (2)

HI (1)

### CA

\* [REDACTED] (b) (4) Kern County, CA 1 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Kern County, CA. Contact: (b) (6), (b) (7)(C), (b) (4),

\* [REDACTED] (b) (4), Imperial County, CA 2 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Yuma County, AZ. Contact: (b) (6), (b) (7)(C), (b) (4)

CBI - DELETED

Monsanto Reference ID  
99-726XRAB

*HI*

\* [REDACTED] (b) (4), Honolulu County, HI 5 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Honolulu County, HI. Contact [REDACTED] (b) (6), (b) (7)(C), (b) (4)



CBI - DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
St. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-726XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 21, 1999

MONSANTO

Food · Health · Hope



**CBI - DELETED**

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

http://www.monsanto.com

Monsanto Reference ID  
99-726XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 21, 1999

99-266-02n

- 1. **USDA Reference Number**
- 2. **Applicant Reference Number** 99-726XRAB
- 3. **Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

[Redacted]

FAX

636/737-7085

Monsanto Company

EEmail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

**4. Duration of Introduction**

Interstate Movement and Release Oct 21, 1999 - Oct 20, 2000

**5. Recipient** Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate Tolerant

Cultivar/ Variety Bobwhite, BW251, AC Barrie

# CBI - DELETED

Monsanto Reference ID  
99-726XRAB

**designation of transformed line:** 33391, 33456, 33463

**Constructs:** PV-TXGT10

**genotype:**

**Gene of Interest**

- \* Promoter: CMoVa/I2 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID  
99-726XRAB

designation of transformed line: 33512

**Constructs:** PV-TXGT12

**genotype:**

**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: M1 -- [ CBI Deleted ]

**Gene of Interest**

- \* Promoter: CMP 3/I5 -- [ CBI Deleted ]
- \* Gene: CTP7-CP4 -- [ CBI Deleted ]
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID  
99-726XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 9000 pounds of wheat seed before and after harvest

<b>ORIGIN:</b>		<b>DESTINATION:</b>	
CA	HI	CA	HI
MO		MO	

Ship From:

CA

\* [REDACTED] (b) (4), Kern County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Kern County, CA (b) (4), (b) (5), (b) (6)

\* [REDACTED] (b) (4), Imperial County, CA

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
Yuma County, AZ, [REDACTED] (b) (6), (b) (7)(C), (b) (4)

HI

[REDACTED] (b) (4), Honolulu County, HI  
(b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Honolulu County, HI, [REDACTED] (b) (6), (b) (7)(C), (b) (4)

MO

\* [REDACTED] (b) (4) St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] St. Louis County, MO, [REDACTED] (b) (6), (b) (7)(C), (b) (4)

Ship To:

CA

Monsanto Reference ID  
99-726XRAB

\* [REDACTED] (b) (4), Kern County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
Kern County, CA, [REDACTED] (b) (6), (b) (7)(C) USA

\* [REDACTED] (b) (4), Imperial County, CA

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4), Yuma  
County, AZ, [REDACTED] (b) (6), (b) (7)(C), (b) (4)

*HI*

\* [REDACTED] (b) (4), Honolulu County, HI  
[REDACTED] (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Honolulu County, HI, [REDACTED] (b) (6), (b) (7)(C), (b) (4)

*MO*

\* [REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
St. Louis County, MO, [REDACTED] (b) (6), (b) (7)(C) U.S.A., [REDACTED] (b) (6), (b) (7)(C), (b) (4)

**Release Sites:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

CA (2) HI (1)

*CA*

\* [REDACTED] (b) (4), Kern County, CA 1 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Kern County, CA. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4),

\* [REDACTED] (b) (4), Imperial County, CA 2 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Yuma County, AZ. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

CBI - DELETED

Monsanto Reference ID  
99-726XRAB

*HI*

\* [REDACTED] (b) (4), Honolulu County, HI 5 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Honolulu County, HI. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

MONSANTO

Food · Health · Hope



CBI - DELETED

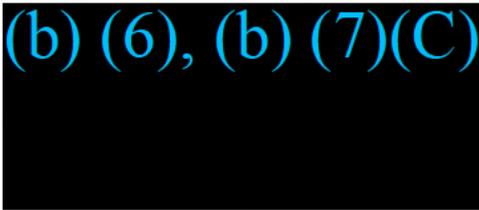
MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-726XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

Sep 21, 1999

file copy

Ms. Barbara Hass, State Regulatory Official  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

September 28, 1999

Dear Ms. Hass:

Enclosed is notification 99-266-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-02n	Applicant #:	99-726XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

file copy

Mr. Myron Isherwood Jr., Manager  
Plant Quarantine Branch  
Hawaii Department of Agriculture  
701 Ilalo Street  
Honolulu, HI 96813

September 28, 1999

Dear Mr. Isherwood Jr.:

Enclosed is notification 99-266-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-02n	Applicant #:	99-726XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

September 28, 1999

Dear Mr. Brown:

Enclosed is notification 99-266-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-02n	Applicant #:	99-726XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Ms. Barbara Hass, State Regulatory Official  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

September 28, 1999

Dear Ms. Hass:

Enclosed is notification 99-266-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-02n	Applicant #:	99-726XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination provided, wheat seed from Missouri is prohibited unless it meets the requirements of Title 3, Calif. Code of Regs., Section 3277, Cereal Leaf Beetle Exterior Quarantine.  
 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Barbara J. Hass (916) 654-1017

Signature: (b) (6), (b) (7)(C)

Date: October 5, 1999

State: California

OCT 7 1999

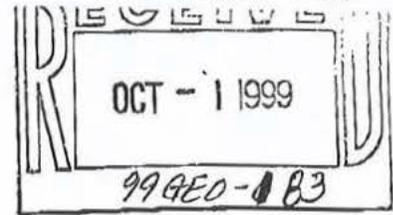




United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737



September 28, 1999

Mr. Myron Isherwood Jr., Manager  
Plant Quarantine Branch  
Hawaii Department of Agriculture  
701 Ilalo Street  
Honolulu, HI 96813

Dear Mr. Isherwood Jr.:

Enclosed is notification 99-266-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-02n	Applicant #:	99-726XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St. Honolulu, HI 96813  
 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 12 October 1999

State: Hawaii





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

September 28, 1999

Dear Mr. Brown:

Enclosed is notification 99-266-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number	99-266-02n	Applicant #:	99-726XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

**(b) (6), (b) (7)(C)**

E. Diane Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: **(b) (6), (b) (7)(C)**

Date: 10/4/99

State: MO



APHIS - Protecting American Agriculture

AN Equal Opportunity Employer

October 25, 1999

(b) (6), (b) (7)(C)  
Monsanto Company  
700 Chesterfield Pkwy N  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C) :

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 25, 1999.

Interstate movement and Release  
Notification no. 99-266-02n (726XRAB)  
Regulated article - Wheat  
Destinations - California, Hawaii, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3 (c). All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of California concurs with APHIS determination; provided, wheat seed from Missouri is prohibited unless it meets the requirements of Title 3, California Code of Regulations, Section 3277, Cereal Leaf Beetle Exterior Quarantine.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
  - a) All planting, pollinating and harvesting dates of each field trial.
  - b) Any changes to the field sites, recommended conditions, or other related matters.
  - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:

OR120018\_BR\_012797

- a) The germination of volunteer wheat after harvest.
- b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.

The report should be submitted to the Plant Quarantine Branch, 701 Ilalo Street, Honolulu, Hawaii, 96813, with a copy to Ms. Carol Okada, within six months of completion or termination of the test.

4. The introduction of any organism other than wheat seeds may be regulated by the Plant Quarantine Branch. For more information on the organisms regulated by the Branch, please contact Mr. Myron Isherwood Jr., Hawaii Department of Agriculture.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations  
Biotechnology Evaluations  
Scientific Services  
Plant Protection and Quarantine

Enclosure

cc:

B. Hass, California Dept. of Food and Agric., Sacramento, CA  
M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
R. Stoaks, PPQ, WR, Sacramento, CA  
D. DeWeese, PPQ, SCR, Jefferson City, MO  
File number 99-266-02n

1999 Wheat Field Trial Report  
USDA # 99-266-02n Monsanto # 99-726XRAB

(b) (6), (b) (7)(C)  
May 8, 2001  
Monsanto Company

Location	County	State
(b) (4)	Imperial	AZ (NOT PLANTED)
(b) (4)	Kern	CA
(b) (4)	Honolulu	HI

Kern County, CA

Planting Date December 8, 1999

Harvest Date: June 25, 2000

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of trial: Crosses

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

Field Monitoring for Plant Stand: (b) (4)

Disposition of the Harvested Material: (b) (4)

General Results of Field Trial: (b) (4)

Honolulu, HI

Planting Date January 24-26, 2000

Harvest Date: April 28-May 9, 2000

Destruct Date: May 15, 2000

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

Field Monitoring for Plant Stand: (b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvest: (b) (4)

Disposition of the harvested material: (b) (4)

General Results of Field Trial: (b) (4)

**CONFIDENTIAL**

**Wheat Field Test Report**  
USDA #99-266-02n                      Monsanto #99-726XRAB

**AMENDED**  
**November 19, 2002**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
7673	Imperial	CA	Not Planted
2147302562	Kern	CA	
7683	Honolulu	HI	

**Kern County/CA (2147302562)**

**Planting Date:** 12/08/1999

**Harvest Date:** 06/25/2000

**Vector Constructs/Line Numbers Planted:** [REDACTED] (b) (4) ] - CBI

**Purpose of Field Trial:** (b) (4) ] - CBI

**Field Monitoring Observations for Disease Susceptibility:** [REDACTED] (b) (4)  
[REDACTED]  
] - CBI

**Field Monitoring Observations for Insect Susceptibility:** [REDACTED] (b) (4)  
[REDACTED]  
] - CBI

**Field Monitoring Observations for Plant Growth Characteristics:** [REDACTED] (b) (4)  
[REDACTED]  
] - CBI

**Field Monitoring Observations for Weediness Characteristics:** [REDACTED] (b) (4)  
[REDACTED]  
] - CBI

Field Monitoring Observations for Plant Stand: [REDACTED] (b) (4)  
[REDACTED] - CBI

Disposition of the Harvested Material: [REDACTED] (b) (4) - CBI

Monitoring for Volunteer Plants: [REDACTED] (b) (4)  
[REDACTED] - CBI

Additional Comments: [REDACTED] (b) (4) - CBI

Honolulu County/HI (7683)

Planting Date: 01/24/2000

Harvest Date: 04/28/2000

Destruct Date: 05/15/2000

Vector Constructs/Line Numbers Planted: [REDACTED] (b) (4)  
[REDACTED] - CBI

Purpose of Field Trial: [REDACTED] (b) (4) - CBI

Field Monitoring Observations for Disease Susceptibility: [REDACTED] (b) (4)  
[REDACTED] - CBI

Field Monitoring Observations for Insect Susceptibility: [REDACTED] (b) (4)  
[REDACTED] - CBI

Field Monitoring Observations for Plant Growth Characteristics: [REDACTED] (b) (4)  
[REDACTED] - CBI

Field Monitoring Observations for Weediness Characteristics: [REDACTED] (b) (4)  
[REDACTED] - CBI

Field Monitoring Observations for Plant Stand: [REDACTED] (b) (4)  
[REDACTED] - CBI

Disposition of the Harvested Material: [REDACTED] (b) (4) - CBI

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [REDACTED] (b) (4)  
[REDACTED] - CBI

Additional Comments: [REDACTED] (b) (4)  
[REDACTED] - CBI

## CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982). *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v Dept. of Health & Human Services*, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. *Greenberg v. Food and Drug Administration*, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); *Worthington Compressors, Inc. v. Costie*, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. *Greenberg v. FDA*, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below\*.

\*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

## Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

#### **Identity and Characteristics of Donor Organisms**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

#### **Identification Of Physical Site And Release Location**

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

#### **Identification Of Items claimed as Confidential Business Information (CBI)**

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

**CBI-DELETED**

**Wheat Field Test Report**  
**USDA #99-266-02n                      Monsanto #99-726XRAB**

**AMENDED**  
**November 19, 2002**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
7673	Imperial	CA	Not Planted
2147302562	Kern	CA	
7683	Honolulu	HI	

**Kern County/CA (2147302562)**

**Planting Date:** 12/08/1999

**Harvest Date:** 06/25/2000

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Monitoring for Volunteer Plants:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]

**Honolulu County/HI (7683)**

**Planting Date:** 01/24/2000

**Harvest Date:** 04/28/2000

**Destruct Date:** 05/15/2000

**Vector Constructs/Line Numbers Planted:** [CBI-Deleted]

**Purpose of Field Trial:** [CBI-Deleted]

**Field Monitoring Observations for Disease Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Insect Susceptibility:** [CBI-Deleted]

**Field Monitoring Observations for Plant Growth Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Weediness Characteristics:** [CBI-Deleted]

**Field Monitoring Observations for Plant Stand:** [CBI-Deleted]

**Disposition of the Harvested Material:** [CBI-Deleted]

**Method of Devitalization or Final Disposition of Plot Area after Harvesting:** [CBI-Deleted]

**Additional Comments:** [CBI-Deleted]



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection  
Service

Plant Protection  
and Quarantine

99-266-0211

From: *Barbara*  
Director's Office,  
Operational Support

Date: 6-26

To: *J. White*

- Prepare reply for DO, DA, OA signature
- Reply directly, please send me a copy
- Please handle
- For your comments
- Discuss with me
- For your information
- Bilateral Issue
- Due July 5

Remarks:

*Ret - to me*

*Kay,*

*See Dianne for 1995 - present  
See Hidsky if he has anything  
prior to '95  
Jim*

6/25/01

(b) (4)

TO: PPG: Barbara Kennedy

REQUESTER:

REQUEST #: FOIA-01-403

DUE TO FOIA: 7-5-01

Attached is a FOIA request for documents maintained by your office. Please conduct a thorough search for all responsive records, including files that may be kept in locations other than your office.

Please complete this page and return it with one single-sided copy of the responsive records to:

**Teresa LaCovey, FOIA Office  
Unit 50, Suite 4B09, Space 4A64**

*Requester wants info you have since 1987. According to him, 1987 is when the compliance program started,*

**DO NOT STAPLE THE DOCUMENTS.**

Search time\* (clerical): \_\_\_\_\_

Search time\* (professional): \_\_\_\_\_

\*Does not include photocopying time

Review time (professional): \_\_\_\_\_

Search Conducted by:

Name	Title	Office and Phone
_____	_____	_____
_____	_____	_____
_____	_____	_____

Missing Document Explanation/Special Notes:

FOIA Liaison's Initials & Date: \_\_\_\_\_

RECEIVED  
JUN 22 2001  
FOIA

# U.S. PIRG Education Fund



## National Association of State PIRGs

June 18, 2001

01-403

6-22-01  
7-23-01

PPA  
VS  
Lef  
6/22/01

- Board of Directors
- Alaska PIRG
- California PIRG
- Colorado PIRG
- Connecticut PIRG
- Florida PIRG
- Illinois PIRG
- Maryland PIRG
- Massachusetts PIRG
- PIRG in Michigan
- Missouri PIRG
- Montana PIRG
- New Jersey PIRG
- New Mexico PIRG
- New York PIRG
- Ohio PIRG
- Oregon State PIRG
- Pennsylvania PIRG
- Vermont PIRG
- Washington PIRG
- Wisconsin PIRG

Kim Pacheco  
 Assistant Director/FOIA Officer  
 4700 River Road, Unit 50  
 Riverdale, MD 20737-1232

Dear Ms. Pacheco:

This letter serves as a formal request under the Freedom of Information Act (5 U.S.C. 552) ("FOIA") for all information related to compliance infractions that have occurred relative to USDA-APHIS regulations for performance standards under notifications or permit conditions for the introduction of genetically engineered organisms. According to page 41 of the Bt-MAIZE section of the recent Council on Environmental Quality ("CEQ") and Office of Science and Technology Policy ("OSTP") document "CEQ and OSTP Assessment: Case Studies of Environmental Regulations for Biotechnology," "From 1995 through 2000, APHIS recorded a total of 63 such compliance infractions." I am requesting all information prior to the 1995-2000 time period, during 1995-2000, and since, related to these infractions, including:

1. The name of the applicant responsible for the infraction.
2. A detailed description of the infraction.
3. Information related to action taken by APHIS in response to the infraction.
4. All paperwork to and from APHIS and the institution responsible for the infraction.

Pursuant to the amendments of the FOIA (providing for a reduction or waiver of fees if it is "in the public interest because furnishing the information can be considered as primarily benefiting the public"), we request such a waiver. Members of U.S. PIRG and the general public are regularly and commonly affected by the science and practices which motivated this request. Responding to the specific criteria for a fee waiver at USDA:

1. These documents describe important information about the violation of critical regulations that protect public health and the environment, as well as describe the adequacies of the government's response to these violations.
2. These documents are important, as described above, yet are not publicly available for review.

3. These documents will be used for research on the subject of regulatory oversight of genetically engineered organisms on behalf of a non-profit organization. I will receive no commercial benefit, nor will my employer, by definition.
4. The information would likely be disseminated in a report that would be available on the web, and to the public upon request in hard copy. I can not fully determine my methods for dissemination without seeing what the document contains. My qualifications include an M.S. in environmental policy, and the release of several other reports in my capacity as an Environmental Advocate for U.S. PIRG.
5. Disclosure of a document fundamental to the oversight of genetic engineering is missing from the public domain. The level of public understanding is accordingly hampered. Dissemination would broaden that understanding significantly.

U.S. PIRG is a national non-profit, non-partisan research and advocacy organization which serves as the national office for a number of affiliated State PIRGs. The PIRGs have addressed major environmental and consumer issues for many years.

As the FOIA provides, we anticipate a response within ten to twenty days. If your office requires further assistance with this request, please do not hesitate to contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

Environmental Advocate

99-266-02N COMPLIANCE INFRACTION CHECKLIST

1. Reported within 24 hours?

Yes

No

2. How reported?

Telephone *Monsanto personnel*

E:mail

Fedex

3. By *(b) (6), (b) (7)(C)*



4. Was the incident reported in a letter within 5 days?

Yes

No

5. If no why not?

6. Describe infraction:

- a. Act of nature
- b. Outside of control of responsible person
- c. Collaborator
- d. Other (explain)

*Accidental spillage while enroute to final destination*

(See other side)

MONSANTO

Food • Health • Hope



May 23, 2000

MONSANTO COMPANY  
700 CHESTERFIELD PKWY NORTH  
CHESTERFIELD, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Ms. Dianne Hatmaker  
Biotechnology Program Operations  
United States Department of Agriculture  
Animal and Plant Health Inspection Service  
4700 River Road  
Riverdale, MD 20737

Re: USDA #99-266-02n

Dear Ms. Hatmaker:

(b) (4)

(b) (4)

OR120018\_BR\_012814

(b) (4)

[Redacted]

[Redacted]

[Redacted]

[Redacted]

Sincerely yours,

(b) (6), (b) (7)(C)

[Redacted]



MONSANTO

Food • Health • Hope



**CONFIDENTIAL**

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63108  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-727XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 21, 1999

99-266-03n

- 1. **USDA Reference Number**
- 2. **Applicant Reference Number**
- 3. **Applicant/Responsible Party**

99-727XRAB

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

**4. Duration of Introduction**

Interstate Movement and Release      Oct 21, 1999 - Oct 20, 2000

**5. Recipient**                      Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:**              HT

**Phenotype:**                          Glyphosate Tolerant

Cultivar Variety Bobwhite, BW251, AC Barrie

# CONFIDENTIAL

Monsanto Reference ID  
99-727XRAB

**designation of transformed line:** 25397

**Constructs:** PV-TXGT05

**genotype:**

**Gene of Interest**

\* Promoter: CMP3/I5 -- [REDACTED] ] - CBI *CBI*

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

\* Promoter: CMoVa/I5 -- [REDACTED] ] - CBI *CBI*

\* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

\* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

# CONFIDENTIAL

Monsanto Reference ID  
99-727XRAB

- 7. **Mode of Transformation**     Particle Bombardment
- 8. **Introduction**                Interstate Movement and Release

Ship up to 9000 pounds wheat seed before and after harvest

<b>ORIGIN:</b>		<b>DESTINATION:</b>	
CA	HI	CA	HI
MO		MO	

**Ship From:**

CA

\* [REDACTED] (b) (4), Kern County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED], Kern County, CA (b) (6), (b) (7)(C)

\* [REDACTED] (b) (4), Imperial County, CA

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
Yuma County, AZ, [REDACTED] (b) (6), (b) (7)(C), (b) (4)

HI

\* [REDACTED] (b) (4), Honolulu County, HI  
[REDACTED] (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED], Honolulu County, HI (b) (6), (b) (7)(C), (b) (4)

MO

\* [REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] St. Louis County, MO, [REDACTED] (b) (6), (b) (7)(C), (b) (4)

**Ship To:**

CA

# CONFIDENTIAL

Monsanto Reference ID  
99-727XRAB

\* [REDACTED] (b) (4), Kern County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
Kern County, CA, (b) (6), (b) (7)(C) USA

\* [REDACTED] (b) (4), Imperial County, CA

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4), Yuma  
County, AZ, (b) (6), (b) (7)(C), (b) (4)

## HI

\* [REDACTED] (b) (4), Honolulu County, HI

(b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Honolulu County, HI, (b) (6), (b) (7)(C), (b) (4)

## MO

[REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
St. Louis County, MO, (b) (6), (b) (7)(C) U.S.A., (b) (6), (b) (7)(C), (b) (4)

## Release Sites:

### NUMBER OF STATES/TERRITORIES AND SITES:

CA (2) HI (1)

#### CA

\* [REDACTED] (b) (4) Kern County, CA 1 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Kern County, CA. Contact: (b) (6), (b) (7)(C), (b) (4)

\* [REDACTED] (b) (4) Imperial County, CA 2 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Yuma County, AZ. Contact: (b) (6), (b) (7)(C), (b) (4)

# CONFIDENTIAL

Monsanto Reference ID  
99-727XRAB

*HI*

\* [REDACTED] (b) (4) Honolulu County, HI 5 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED], Honolulu County, HI. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

MONSANTO



Food · Health · Hope

**CONFIDENTIAL**

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-727XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company  
Sep 21, 1999

## CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential concerns the description of the gene introduced into corn and/or the variety into which they were transformed. The gene description category includes the names and information about genes, promoters and expressed traits.

### Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.

### Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many person years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of high solid, insect, fungal, and virus resistant crops for more than 10 years, and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the person hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this FOIA request, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the CBI Justification expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include Rhone-Poulenc, ICI, and Ciba-Geigy.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **Names And Information About Genes, Promoters, And Expressed Traits**

The release of information about the genes and promoters in the vectors will directly provide *competitors* with the knowledge of the *precise* genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the *competitors* will have access to the structure of the Monsanto products, with the consequences outlined above. Patents *for* the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **Identity And Characteristics Of Donor Organism**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identity of Recipient Cultivars**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organism has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

### **Identification of Items claimed as Confidential Business Information**

Items claimed as CBI as so indicated in the text as follows: [ CBI - Deleted ]. A non-confidential copy of the application is also included with the confidential item enclosed in brackets, “[ ]”, as labeled as CBI.

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CBI - DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-727XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 21, 1999

99-266-03n

- 1. USDA Reference Number
- 2. Applicant Reference Number
- 3. Applicant/Responsible Party

99-727XRAB

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

4. Duration of Introduction

Interstate Movement and Release Oct 21, 1999 - Oct 20, 2000

5. Recipient Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar Variety Bobwhite, BW251, AC Barric

# CBI - DELETED

Monsanto Reference ID  
99-727XRAB

**designation of transformed line:** 25397

**Constructs:** PV-TXGT05

**genotype:**

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: CMoVa/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

# CBI - DELETED

Monsanto Reference ID  
99-727XRAB

**7. Mode of Transformation** Particle Bombardment

**8. Introduction** Interstate Movement and Release

Ship up to 9000 pounds wheat seed before and after harvest

<b>ORIGIN:</b>			<b>DESTINATION:</b>		
CA		HI	CA		HI
MO			MO		

**Ship From:**

CA

\* [REDACTED] (b) (4), Kern County, CA (b) (4)

CONTACT: (b) (6), (b) (7)(C), (b) (4) [REDACTED]  
[REDACTED], Kern County, CA (b) (6), (b) (7)(C)

[REDACTED] (b) (4), Imperial County, CA

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
Yuma County, AZ, (b) (6), (b) (7)(C), (b) (4)

HI

[REDACTED] (b) (4), Honolulu County, HI  
(b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Honolulu County, HI, (b) (6), (b) (7)(C), (b) (4)

MO

\* [REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] St. Louis County, MO (b) (6), (b) (7)(C), (b) (4)

**Ship To:**

CA

# CBI - DELETED

Monsanto Reference ID  
99-727XRAB

\* [REDACTED] (b) (4), Kern County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
Kern County, CA, [REDACTED] (b) (6), (b) (7)(C) USA

\* [REDACTED] (b) (4), Imperial County, CA

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4), Yuma  
County, AZ, [REDACTED] (b) (6), (b) (7)(C), (b) (4)

## HI

[REDACTED] (b) (4), Aiea, Honolulu County, HI  
(b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Honolulu County, HI, [REDACTED] (b) (6), (b) (7)(C), (b) (4)

## MO

\* [REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
St. Louis County, MO, [REDACTED] (b) (6), (b) (7)(C) U.S.A., [REDACTED] (b) (6), (b) (7)(C), (b) (4)

## Release Sites:

### NUMBER OF STATES/TERRITORIES AND SITES:

CA (2)

HI (1)

#### CA

\* [REDACTED] (b) (4), Kern County, CA 1 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Kern County, CA. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4),

\* [REDACTED] (b) (4) Imperial County, CA 2 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Yuma County, AZ. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

# CBI - DELETED

Monsanto Reference ID  
99-727XRAB

*HI*

\* [REDACTED] (b) (4), Honolulu County, HI 5 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Honolulu County, HI. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

MONSANTO

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CBI - DELETED

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-727XRAB

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

Sep 21, 1999

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MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
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Monsanto Reference ID  
99-727XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

Sep 21, 1999

99-266-03n

**1. USDA Reference Number**

**2. Applicant Reference Number** 99-727XRAB

**3. Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

FAX

636/737-7085

Monsanto Company

EMail

(b) (6), (b) (7)(C)@monsanto.com

700 Cheserfield Parkway North

St. Louis, MO

**4. Duration of Introduction**

Interstate Movement and Release Oct 21, 1999 - Oct 20, 2000

**5. Recipient** Wheat, Triticum aestivum

**6. Regulated Article**

**Phenotypic Category:** HT

**Phenotype:** Glyphosate Tolerant

Cultivar Variety Bobwhite, BW251, AC Barrie

Monsanto Reference ID  
99-727XRAB

designation of transformed line: 25397

**Constructs:** PV-TXGT05

**genotype:**

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

**Gene of Interest**

- \* Promoter: CMoVa/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

Monsanto Reference ID  
99-727XRAB

7. Mode of Transformation     Particle Bombardment

8. Introduction                     Interstate Movement and Release

Ship up to 9000 pounds wheat seed before and after harvest

<b>ORIGIN:</b>			<b>DESTINATION:</b>		
CA		HI	CA		HI
MO			MO		

**Ship From:**

CA

\* [REDACTED] (b) (4), Kern County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Kern County, CA, (b) (6), (b) (7)(C)

\* [REDACTED] (b) (4) Imperial County, CA

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
Yuma County, AZ, (b) (6), (b) (7)(C), (b) (4)

HI

\* [REDACTED] (b) (4), Honolulu County, HI  
(b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Honolulu County, HI, (b) (6), (b) (7)(C), (b) (4)

MO

\* [REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] St. Louis County, MO (b) (6), (b) (7)(C), (b) (4)

**Ship To:**

CA

Monsanto Reference ID  
99-727XRAB

\* [REDACTED] (b) (4), Kern County, CA (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
Kern County, CA, (b) (6), (b) (7)(C) USA

\* [REDACTED] (b) (4), Imperial County, CA

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4), Yuma  
County, AZ, (b) (6), (b) (7)(C), (b) (4)

*HI*

[REDACTED] (b) (4) Honolulu County, HI  
(b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Honolulu County, HI, (b) (6), (b) (7)(C), (b) (4)

*MO*

[REDACTED] (b) (4), St. Louis County, MO (b) (4)

CONTACT: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
St. Louis County, MO, (b) (6), (b) (7)(C) U.S.A. (b) (6), (b) (7)(C), (b) (4)

**Release Sites:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

CA (2) HI (1)

*CA*

\* [REDACTED] (b) (4), Kern County, CA 1 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Kern County, CA. Contact: (b) (6), (b) (7)(C), (b) (4),

\* [REDACTED] (b) (4) Imperial County, CA 2 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Yuma County, AZ. Contact: (b) (6), (b) (7)(C), (b) (4)

CBI - DELETED

Monsanto Reference ID  
99-727XRAB

*HI*

\* [REDACTED] (b) (4), Honolulu County, HI 5 acres.

RESPONSIBLE PERSON/RESEARCHER: [REDACTED] (b) (6), (b) (7)(C), (b) (4)  
[REDACTED] Honolulu County, HI. Contact: [REDACTED] (b) (6), (b) (7)(C), (b) (4)

file copy

Ms. Barbara Hass, State Regulatory Official  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

September 28, 1999

Dear Ms. Hass:

Enclosed is notification 99-266-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-03n	Applicant #:	99-727XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

file copy

Mr. Myron Isherwood Jr., Manager  
Plant Quarantine Branch  
Hawaii Department of Agriculture  
701 Ilalo Street  
Honolulu, HI 96813

September 28, 1999

Dear Mr. Isherwood Jr.:

Enclosed is notification 99-266-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-03n	Applicant #:	99-727XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

OR120018\_BR\_012838

file copy

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

September 28, 1999

Dear Mr. Brown:

Enclosed is notification 99-266-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-03n	Applicant #:	99-727XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
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Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Ms. Barbara Hass, State Regulatory Official  
California Department of Food and Agriculture  
1220 N Street - Rm A-372  
Sacramento, CA 95814

September 28, 1999

Dear Ms. Hass:

Enclosed is notification 99-266-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-03n	Applicant #:	99-727XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dwayne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination provided, wheat seed from Missouri is prohibited unless it meets the requirements of Title 3, Calif. Code of Regs., Section 3277, Cereal Leaf  
 State DOES NOT CONCUR and offers the following reasons: Beetle Exterior Quarantine.

Name of State official: Barbara J. Hass (916) 654-1017

Signature: (b) (6), (b) (7)(C)

Date: October 5, 1999

State: California



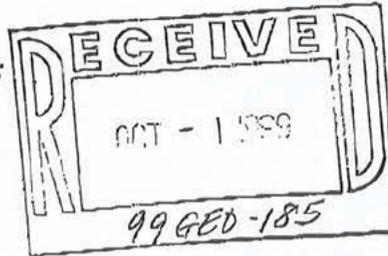


United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager  
Plant Quarantine Branch  
Hawaii Department of Agriculture  
701 Ilalo Street  
Honolulu, HI 96813



September 28, 1999

Dear Mr. Isherwood Jr.:

Enclosed is notification 99-266-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-03n	Applicant #:	99-727XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination. Please notify Ms. Carol Okada,  
Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813  
 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 12 October 1999

State: Hawaii





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Michael Brown  
Plant Industries Division  
Missouri Department of Agriculture  
1616 Missouri Boulevard  
Jefferson City, MO 65102

September 28, 1999

Dear Mr. Brown:

Enclosed is notification 99-266-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-266-03n	Applicant #:	99-727XRAB
Received:	September 23, 1999	Effective:	October 23, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CA HI MO		
Release destination:	CA HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 10/4/99

State: MO



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

October 25, 1999

(b) (6), (b) (7)(C)  
Monsanto Company  
700 Chesterfield Pkwy N  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after October 25, 1999.

Interstate movement and Release  
Notification no. 99-266-03n (727XRAB)  
Regulated article - Wheat  
Destinations - California, Hawaii, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3 (c). All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of California concurs with APHIS determination; provided, wheat seed from Missouri is prohibited unless it meets the requirements of Title 3, California Code of Regulations, Section 3277, Cereal Leaf Beetle Exterior Quarantine.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
  - a) All planting, pollinating and harvesting dates of each field trial.
  - b) Any changes to the field sites, recommended conditions, or other related matters.
  - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:

OR120018\_BR\_012843

- a) The germination of volunteer wheat after harvest.
- b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.

The report should be submitted to the Plant Quarantine Branch, 701 Ilalo Street, Honolulu, Hawaii, 96813, with a copy to Ms. Carol Okada, within six months of completion or termination of the test.

4. The introduction of any organism other than wheat seeds may be regulated by the Plant Quarantine Branch. For more information on the organisms regulated by the Branch, please contact Mr. Myron Isherwood Jr., Hawaii Department of Agriculture.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations  
Biotechnology Evaluations  
Scientific Services  
Plant Protection and Quarantine

Enclosure

cc:

B. Hass, California Dept. of Food and Agric., Sacramento, CA  
M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI  
M. Brown, Missouri Dept. of Agric., Jefferson City, MO  
R. Stoaks, PPQ, WR, Sacramento, CA  
D. DeWeese, PPQ, SCR, Jefferson City, MO  
File number 99-266-03n

*No CBI*

**Wheat Field Test Report**  
**USDA #99-266-03n : Monsanto #99-727XRAB**

**November 14, 2002**

**Biotech Field Compliance Team**  
**Monsanto Company**

<u>Location</u>	<u>County</u>	<u>State</u>	
7673	Imperial	CA	Not Planted
2147302562	Kern	CA	Not Planted
7683	Honolulu	HI	Not Planted

Bp number: 99-039-16n

App number: 99-056XRAB  
 Received: 2/08/99  
 Institution: Monsanto  
 Recipient: Wheat  
 Status: Pending  
 Effective date: 3/10/99  
 Phenotype: HT - Glyphosate tolerant  
 Comments:  
 Resp person: **(b) (6), (b) (7)(C)**  
 Parsed name:  
 Address1: Monsanto Company  
 Address2: 700 Chesterfield Parkway North  
 Address3:  
 Address4:  
 City/State/Zip: St. Louis, MO 63198  
 Telephone: **(b) (6), (b) (7)(C)**  
 Begin movement: 3/07/99  
 End movement: 3/06/00  
 Begin release: 3/07/99  
 End release: 3/06/00  
 Acre: 24.00  
 CBI status: CBI  
 Fax: 314-737-7085

- |  | Initial | Date               |
|--|---------|--------------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ ajd ] | [ 2/10/99 ]        |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist               | [ KH ]* | [ ]*               |
| 3. <input checked="" type="checkbox"/> Letter of notification to State         | [ bgs ] | [ 2/11/99 ]* fed x |
| 4. <input type="checkbox"/> State response                                     |         |                    |

O/d	Loc	Site	Reg		
Interstate	*Dest*CO	*	*WR	*	[ ] [ ]
Interstate	*Dest*ID	*	*WR	*	[ ] [ ]
Interstate	*Dest*MT	*	*WR	*	[ ] [ ]
Interstate	*Dest*ND	*	*SCR	*	[ ] [ ]
Interstate	*Dest*SD	*	*SCR	*	[ ] [ ]
Interstate	*Dest*WA	*	*WR	*	[ ] [ ]
Interstate	*Orig*MO	*	*SCR	*	[ ] [ ]
Interstate	*Orig*ND	*	*SCR	*	[ ] [ ]
Release	*CO	*	1*WR	*	[ ] [ ]
Release	*ID	*	1*WR	*	[ ] [ ]
Release	*MT	*	1*WR	*	[ ] [ ]
Release	*ND	*	2*SCR	*	[ ] [ ]
Release	*SD	*	1*SCR	*	[ ] [ ]
Release	*WA	*	2*WR	*	[ ] [ ]

- |  |         |                    |
|--|---------|--------------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database                 | [ ajd ] | [ 2/10/99 ]        |
| 6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw | [ bgs ] | [ 2/22/99 ]* fed x |
| 7. <input checked="" type="checkbox"/> Enter final data into database            | [ bgs ] | [ 2/24/99 ]        |

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Food • Health • Hope



**CONFIDENTIAL**

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-056XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

05-Feb-99

- 1. **USDA Reference Number** 99-039-16n
- 2. **Applicant Reference Number** 99-056XRAB
- 3. **Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Village Pkwy  
St. Louis, MO 63198

Phone (b) (6), (b) (7)(C)  
 FAX 314-737-7085  
 EMail (b) (6), (b) (7)(C)@monsanto.com

**4. Duration of Introduction**

Interstate Movement and Release 3/7/99 - 3/6/2000

- 5. **Recipient** Wheat, Triticum aestivum
- 6. **Regulated Article**

**Phenotypic Category:** HT  
**Phenotype** Glyphosate Tolerant

# CONFIDENTIAL

Monsanto Reference ID  
99-056XRAB

**designation of transformed line:** 33391, 33456, 33463

**Constructs:** PV-TXGT10

**genotype:**

**Gene of Interest**

\* Promoter: CMP3/I5 -- (b) (4) CBI  
(b) (4)

\* Gene: CTP2-CP4 -- (b) (4) CBI  
(b) (4)

\* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**Gene of Interest**

\* Promoter: CMoVa/I2 -- (b) (4) CBI  
(b) (4)

\* Gene: CTP2-CP4 -- (b) (4) CBI  
(b) (4)

\* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

# CONFIDENTIAL

Monsanto Reference ID  
99-056XRAB

designation of transformed line: 31849

Constructs: PV-TXGT11

genotype:

Gene of Interest

\* Promoter: CMP 3/I5 -- (b) (4) CBI  
(b) (4)  
\* Gene: CTP2-CP4 -- (b) (4) CBI  
(b) (4)  
\* Terminator: NOS 3'+2 -- (b) (4) CBI  
(b) (4)

Gene of Interest

\* Promoter: CMoVa/I5 + leader1 -- (b) (4) CBI  
(b) (4)  
\* Gene: CTP2-CP4 -- (b) (4) CBI  
(b) (4)  
\* Terminator: M1 3' - (b) (4) CBI  
(b) (4)

# CONFIDENTIAL

Monsanto Reference ID  
99-056XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

genotype:

Gene of Interest

\* Promoter: MP4 -- (b) (4)  
(b) (4) CBI

\* Gene: CTP2-CP4 -- (b) (4)  
(b) (4) CBI

\* Terminator: M1 -- (b) (4)  
(b) (4) CBI

Gene of Interest

\* Promoter: CMP 3/15 -- (b) (4)  
(b) (4) CBI

\* Gene: CTP7-CP4 -- (b) (4)  
(b) (4) CBI

\* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

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Monsanto Reference ID  
99-056XRAB

7. **Mode of Transformation**                      Disarmed Agrobacterium tumefaciens

8. **Introduction**                                      Interstate Movement and Release

Ship up to 40 pounds of wheat seed in up to 4 shipments to each location.

ORIGIN:		DESTINATION:		
MO		CO		ID
	ND	MT		ND
		Not		SD
		WA		

**Ship From:**

*MO*

(b) (4) St. Louis County, MO (b) (4) U.S.A

*ND*

\* (b) (4), (b) (6), (b) (7)(C) Fargo, Cass County, ND (b) (4), (b) (6), (b) (7)(C)

**Ship To:**

*CO*

\* (b) (4), (b) (6), (b) (7)(C) (b) (4) Weld County, CO,  
(b) (4), (b) (4), (b) (6), (b) (7)(C)

*ID*

(b) (4), (b) (6), (b) (7)(C) (b) (4) Ada County, ID, (b) (4)

*MT*

(b) (4), (b) (6), (b) (7)(C) (b) (4) Cascade County, MT, (b) (4) (b) (4), (b) (6), (b) (7)(C)

*CONFIDENTIAL*

Monsanto Reference ID  
99-056XRAB

**ND**

(b) (4), (b) (6), (b) (7)(C) Cass County, ND, (b) (4), (b) (6), (b) (7)(C)

**North Dakota**

(b) (4), (b) (6), (b) (7)(C) (b) (4) Ward County, North Dakota U.S.A., (b) (4), (b) (6), (b) (7)(C)

**SD**

(b) (4), (b) (6), (b) (7)(C) Roberts County, SD (b) (4), (b) (6), (b) (7)(C)

**WA**

(b) (4), (b) (6), (b) (7)(C) (b) (4) Walla Walla County, WA,  
(b) (4), (b) (6), (b) (7)(C) (b) (4)

(b) (4), (b) (6), (b) (7)(C) (b) (4) Adams County, WA, (b) (4)

**Release Sites:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

CO(1)	ID(1)	MT(1)	ND(1)
North	SD(1)	WA(2)	
Dakota(1)			

**CO**

\* (b) (4) Weld County, CO. Contact: (b) (4), (b) (6), (b) (7)(C)

Release Location: (b) (4) Weld County, CO Up to 4 acres.

**ID**

\* (b) (4) Ada County, ID. Contact: (b) (4), (b) (6), (b) (7)(C)

Release Location: Canyon County, ID Up to 4 acres.

**MT**

\* (b) (4) Cascade County, MT. Contact: (b) (4), (b) (6), (b) (7)(C)

Release Location: Pondera County, MT Up to 4 acres.

# CONFIDENTIAL

Monsanto Reference ID  
99-056XRAB

## ND

\* (b) (4), (b) (6), (b) (7)(C) Cass County, ND (b) (4), (b) (6), (b) (7)(C)  
Release Location: Cass County, ND Up to 4 acres.

## North Dakota

\* (b) (4) Ward County, North Dakota. Contact (b) (4), (b) (6), (b) (7)(C)  
Release Location: (b) (4) Ward County, North Dakota Up to 4 acres.

## SD

\* (b) (4), (b) (6), (b) (7)(C) Roberts County, SD (b) (4), (b) (6), (b) (7)(C)  
Release Location: Roberts County, SD Up to 4 acres.

## WA

\* (b) (4), (b) (6), (b) (7)(C) (b) (4) Walla Walla County, WA. Contact: (b) (4), (b) (6), (b) (7)(C)  
Release Location: (b) (4) Walla Walla County, WA Up to 4 acres.

(b) (4), (b) (6), (b) (7)(C) Whitman County, WA. Contact: (b) (4), (b) (6), (b) (7)(C)  
Release Location: (b) (4), (b) (6), (b) (7)(C) Whitman County, WA Up to 4 acres.

MONSANTO



Food · Health · Hope

**CONFIDENTIAL**

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID  
99-056XRAB

## 9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company  
05-Feb-99

## CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

### LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.<sup>1</sup>

#### GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

<sup>1</sup> In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

### **NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS**

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

### **IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM**

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.



MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

Monsanto Reference ID  
99-056XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

05-Feb-99

- 99-039-16n
1. **USDA Reference Number**
  2. **Applicant Reference Number** 99-056XRAB
  3. **Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Chesterfield Village Pkwy N  
St. Louis, MO 63198

4. **Duration of Introduction**

Interstate Movement and Release 3/7/99 - 3/6/2000

5. **Recipient** Wheat, Triticum aestivum

6. **Regulated Article**

**Phenotypic Category:** HT

**Phenotype** Glyphosate Tolerant

Monsanto Reference ID  
99-056XRAB

**designation of transformed line:** 33391, 33456, 33463

**Constructs:** PV-TXGT10

**genotype:**

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- [ CBI Deleted ]
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**Gene of Interest**

- \* Promoter: CMoVa/I2 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- [ CBI Deleted ]
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID  
99-056XRAB

**designation of transformed line:** 31849

**Constructs:** PV-TXGT11

**genotype:**

**Gene of Interest**

- \* Promoter: CMP 3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- [ CBI Deleted ]
- \* Terminator: NOS 3' +2 -- [ CBI Deleted ]

**Gene of Interest**

- \* Promoter: CMoVa/I5 + leader1 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- [ CBI Deleted ]
- \* Terminator: M1 3' -- [ CBI Deleted ]

Monsanto Reference ID  
99-056XRAB

**designation of transformed line:** 33512

**Constructs:** PV-TXGT12

**genotype:**

**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- [ CBI Deleted ]
- \* Terminator: M1 -- [ CBI Deleted ]

**Gene of Interest**

- \* Promoter: CMP 3/15 -- [ CBI Deleted ]
- \* Gene: CTP7-CP4 -- [ CBI Deleted ]
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID  
99-056XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 40 pounds of wheat seed in up to 4 shipments to each location.

ORIGIN:		DESTINATION:		
MO	ND	CO	ID	
		MT	ND	
		Ne	SD	
		WA		

Ship From:

MO

(b) (4) St. Louis County, MO, (b) (4) J.S.A

ND

\* (b) (6), (b) (7)(C), (b) (4) Cass County, ND, (b) (6), (b) (7)(C), (b) (4)

Ship To:

CO

(b) (6), (b) (7)(C), (b) (4) (b) (4) Weld County, CO,  
(b) (4) (b) (6), (b) (7)(C), (b) (4)

ID

(b) (6), (b) (7)(C), (b) (4) (b) (4) Ada County, ID, (b) (4)

MT

(b) (6), (b) (7)(C), (b) (4) (b) (4) Cascade County, MT, (b) (4) (b) (6), (b) (7)(C), (b) (4)

ND

\* (b) (6), (b) (7)(C), (b) (4) Cass County, ND, (b) (6), (b) (7)(C), (b) (4)

North Dakota

\* (b) (6), (b) (7)(C), (b) (4) (b) (4) Ward County, North Dakota U.S.A., (b) (6), (b) (7)(C), (b) (4)

Monsanto Reference ID  
99-056XRAB

**SD**

\* (b) (6), (b) (7)(C), (b) (4) [redacted] Roberts County, SD, (b) (6), (b) (7)(C), (b) (4) [redacted]

**WA**

(b) (6), (b) (7)(C), (b) (4) [redacted] (b) (4) [redacted] Walla Walla County, WA,  
99362 (b) (6), (b) (7)(C), (b) (4) [redacted]

(b) (6), (b) (7)(C), (b) (4) [redacted] (b) (4) [redacted] Adams County, WA, (b) (4) [redacted]

**Release Sites:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

CO(1)	ID(1)	MT(1)	ND(1)
North	SD(1)	WA(2)	
Dakota(1)			

**CO**

\* (b) (6), (b) (7)(C), (b) (4) [redacted] Weld County, CO. Contact: (b) (6), (b) (7)(C), (b) (4) [redacted]

Release Location: (b) (4) [redacted] Weld County, CO Up to 4 acres.

**ID**

\* (b) (6), (b) (7)(C), (b) (4) [redacted] Ada County, ID. Contact: (b) (6), (b) (7)(C), (b) (4) [redacted]

Release Location: Canyon County, ID Up to 4 acres.

**MT**

\* (b) (6), (b) (7)(C), (b) (4) [redacted] Cascade County, MT. Contact: (b) (6), (b) (7)(C), (b) (4) [redacted]

Release Location: Pondera County, MT Up to 4 acres.

**ND**

\* (b) (6), (b) (7)(C), (b) (4) [redacted] Cass County, ND, (b) (6), (b) (7)(C), (b) (4) [redacted]

Release Location: Cass County, ND Up to 4 acres.

**North Dakota**

\* (b) (6), (b) (7)(C), (b) (4) [redacted] Ward County, North Dakota. Contact: (b) (6), (b) (7)(C), (b) (4) [redacted]

Release Location: (b) (4) [redacted] Ward County, North Dakota Up to 4 acres.

Monsanto Reference ID  
99-056XRAB

**SD**

\* (b) (6), (b) (7)(C), (b) (4) Roberts County, SD (b) (6), (b) (7)(C), (b) (4)

Release Location: Roberts County, SD Up to 4 acres.

**WA**

\* (b) (6), (b) (7)(C), (b) (4) Walla Walla County, WA. Contact: (b) (6), (b) (7)(C), (b) (4)  
(b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Walla Walla County, WA Up to 4 acres.

\* (b) (6), (b) (7)(C), (b) (4) Whitman County, WA. Contact: (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4) Whitman County, WA Up to 4 acres.

MONSANTO

Food • Health • Hope



**CBI DELETED**

Monsanto Reference ID  
99-056XRAB

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

**(b) (6), (b) (7)(C)**

Monsanto Company

05-Feb-99

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MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
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Monsanto Reference ID  
99-056XRAB

Permit Unit  
USDA, APHIS, PPQ, BSS  
4700 River Rd.  
Riverdale, MD 20737

05-Feb-99

99-039-16n

1. **USDA Reference Number**

2. **Applicant Reference Number** 99-056XRAB

3. **Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

314-737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company  
700 Chesterfield Village Pkwy N  
St. Louis, MO 63198

4. **Duration of Introduction**

Interstate Movement and Release 3/7/99 - 3/6/2000

5. **Recipient** Wheat, Triticum aestivum

6. **Regulated Article**

**Phenotypic Category:** HT

**Phenotype** Glyphosate Tolerant

Monsanto Reference ID  
99-056XRAB

**designation of transformed line:** 31849

**Constructs:** PV-TXGT11

**genotype:**

**Gene of Interest**

- \* Promoter: CMP 3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- [ CBI Deleted ]
- \* Terminator: NOS 3' +2 -- [ CBI Deleted ]

**Gene of Interest**

- \* Promoter: CMoVa/I5 + leader1 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- [ CBI Deleted ]
- \* Terminator: M1 3' -- [ CBI Deleted ]

Monsanto Reference ID  
99-056XRAB

**designation of transformed line:** 33391, 33456, 33463

**Constructs:** PV-TXGT10

**genotype:**

**Gene of Interest**

- \* Promoter: CMP3/I5 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- [ CBI Deleted ]
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

**Gene of Interest**

- \* Promoter: CMoVa/I2 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- [ CBI Deleted ]
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID  
99-056XRAB

**designation of transformed line:** 33512

**Constructs:** PV-TXGT12

**genotype:**

**Gene of Interest**

- \* Promoter: MP4 -- [ CBI Deleted ]
- \* Gene: CTP2-CP4 -- [ CBI Deleted ]
- \* Terminator: M1 -- [ CBI Deleted ]

**Gene of Interest**

- \* Promoter: CMP 3/I5 -- [ CBI Deleted ]
- \* Gene: CTP7-CP4 -- [ CBI Deleted ]
- \* Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Monsanto Reference ID  
99-056XRAB

**7. Mode of Transformation**                      Disarmed *Agrobacterium tumefaciens*

**8. Introduction**                                      Interstate Movement and Release

Ship up to 40 pounds of wheat seed in up to 4 shipments to each location.

ORIGIN:	DESTINATION:
MO	CO
ND	MT
	ND
	SD
	WA

**Ship From:**

*MO*

(b) (4) St. Louis County, MO, (b) (4) U.S.A

*ND*

\* (b) (6), (b) (7)(C), (b) (4) Cass County, ND, (b) (6), (b) (7)(C), (b) (4)

**Ship To:**

*CO*

(b) (6), (b) (7)(C), (b) (4) (b) (4) Weld County, CO,  
(b) (4) (b) (6), (b) (7)(C), (b) (4)

*ID*

(b) (6), (b) (7)(C), (b) (4) (b) (4) Ada County, ID, (b) (4)

*MT*

(b) (6), (b) (7)(C), (b) (4) (b) (4) Cascade County, MT, (b) (4) (b) (6), (b) (7)(C), (b) (4)

*ND*

\* (b) (6), (b) (7)(C), (b) (4) Fargo, Cass County, ND, (b) (6), (b) (7)(C), (b) (4)

*North Dakota*

(b) (6), (b) (7)(C), (b) (4) (b) (4) Ward County, North Dakota U.S.A. (b) (6), (b) (7)(C), (b) (4)

Monsanto Reference ID  
99-056XRAB

**SD**

\* (b) (6), (b) (7)(C), (b) (4) [redacted] Roberts County, SD (b) (6), (b) (7)(C), (b) (4) [redacted]

**WA**

\* (b) (6), (b) (7)(C), (b) (4) [redacted] (b) (4) [redacted] Walla Walla County, WA,  
(b) (4) (b) (6), (b) (7)(C), (b) (4) [redacted]

(b) (6), (b) (7)(C), (b) (4) [redacted] (b) (4) [redacted] Adams County, WA, (b) (4) [redacted]

**Release Sites:**

**NUMBER OF STATES/TERRITORIES AND SITES:**

CO(1)	ID(1)	MT(1)	ND(1)
North Dakota(1)	SD(1)	WA(2)	

**CO**

\* (b) (6), (b) (7)(C), (b) (4) [redacted] (b) (4) [redacted] Weld County, CO. Contact: (b) (6), (b) (7)(C), (b) (4) [redacted]

Release Location: (b) (4) [redacted] Weld County, CO Up to 4 acres.

**ID**

\* (b) (6), (b) (7)(C), (b) (4) [redacted] (b) (4) [redacted] Ada County, ID. Contact: (b) (6), (b) (7)(C), (b) (4) [redacted]

Release Location: Canyon County, ID Up to 4 acres.

**MT**

\* (b) (6), (b) (7)(C), (b) (4) [redacted] (b) (4) [redacted] Cascade County, MT. Contact: (b) (6), (b) (7)(C), (b) (4) [redacted]

Release Location: Pondera County, MT Up to 4 acres.

**ND**

\* (b) (6), (b) (7)(C), (b) (4) [redacted] (b) (6), (b) (7)(C), (b) (4) [redacted] Cass County, ND

Release Location: Cass County, ND Up to 4 acres.

**North Dakota**

\* (b) (4) [redacted] (b) (4) [redacted] Ward County, North Dakota. Contact: (b) (6), (b) (7)(C), (b) (4) [redacted]

Release Location: (b) (4) [redacted] Ward County, North Dakota Up to 4 acres.

Monsanto Reference ID  
99-056XRAB

**SD**

\* (b) (6), (b) (7)(C), (b) (4) Roberts County, SD (b) (6), (b) (7)(C), (b) (4)

Release Location: Roberts County, SD Up to 4 acres.

**WA**

\* (b) (6), (b) (7)(C), (b) (4) Walla Walla County, WA. Contact: (b) (6), (b) (7)(C), (b) (4)  
(b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (4) Walla Walla County, WA Up to 4 acres.

\* (b) (6), (b) (7)(C), (b) (4) Whitman County, WA. Contact: (b) (6), (b) (7)(C), (b) (4) (b) (6), (b) (7)(C), (b) (4)

Release Location: (b) (6), (b) (7)(C), (b) (4) Whitman County, WA Up to 4 acres.

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**CBI DELETED**

Monsanto Reference ID  
99-056XRAB

MONSANTO COMPANY  
700 CHESTERFIELD PARKWAY NORTH  
ST. LOUIS, MISSOURI 63198  
PHONE (314) 694-1000  
<http://www.monsanto.com>

**9. Certification**

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company  
05-Feb-99

file copy

Mr. Mitch Yergert  
Colorado Department of Agriculture  
700 Kipling Street - Suite 4000  
Lakewood, CO 80215-5894

February 10, 1999

Dear Mr. Yergert:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-16n	Applicant #:	99-056XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

OR120018\_BR\_012382

file copy

Dr. Rogelio R. Vega  
Division of Plant Industries  
Idaho Department of Agriculture  
2270 Old Penitentiary Road  
Boise, ID 83712

February 10, 1999

Dear Dr. Vega:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-16n	Applicant #:	99-056XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

OR120018\_BR\_012383

file copy

Dr. Gary Gingery, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

February 10, 1999

Dear Dr. Gingery:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-16n	Applicant #:	99-056XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

OR120018\_BR\_012384

file copy

Mr. David R. Nelson, State Entomologist  
North Dakota Department of Agriculture  
600 East Boulevard, 6th Floor  
Bismarck, ND 58505-0020

February 10, 1999

Dear Mr. Nelson:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 99-039-16n Applicant #: 99-056XRAB  
Received: February 8, 1999 Effective: March 10, 1999  
Institution: Monsanto Recipient: Wheat  
Interstate destination: CO ID MT ND SD WA  
Release destination: CO ID MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

OR120018\_BR\_012385

file copy

Mr. Kevin Fridley  
Division of Agricultural Services  
South Dakota Department of Agriculture  
Foss Building-523 East Capitol  
Pierre, SD 57501-3182

February 10, 1999

Dear Mr. Fridley:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 99-039-16n Applicant #: 99-056XRAB  
Received: February 8, 1999 Effective: March 10, 1999  
Institution: Monsanto Recipient: Wheat  
Interstate destination: CO ID MT ND SD WA  
Release destination: CO ID MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

February 10, 1999

Dear Mr. Wessels:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-16n	Applicant #:	99-056XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

---

STATE RESPONSE TO NOTIFICATION

\_\_\_\_\_ State concurs with APHIS determination.

\_\_\_\_\_ State DOES NOT CONCUR and offers the following reasons:

Name of State official: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

State: \_\_\_\_\_

OR120018\_BR\_012387



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Mitch Yergert  
Colorado Department of Agriculture  
700 Kipling Street - Suite 4000  
Lakewood, CO 80215-5894

6661 21 99  
FEB 12 1999  
RECEIVED  
FEB 10, 1999

Dear Mr. Yergert:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 99-039-16n Applicant #: 99-056XRAB  
Received: February 8, 1999 Effective: March 10, 1999  
Institution: Monsanto Recipient: Wheat  
Interstate destination: CO ID MT ND SD WA  
Release destination: CO ID MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mitchell Yergert

Signature: (b) (6), (b) (7)(C)

Date: February 12, 1999

State: Colorado



2/12/99



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Dr. Rogelio R. Vega  
Division of Plant Industries  
Idaho Department of Agriculture  
2270 Old Penitentiary Road  
Boise, ID 83712

February 10, 1999

RECEIVED

FEB 12 1999

PLANT INDUSTRIES

Dear Dr. Vega:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-16n	Applicant #:	99-056XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Signature: (b) (6), (b) (7)(C)

Date: Feb. 16, 1999

State: IDAHO



2-16-99



United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MO 20737

Dr. Gary Gingery, Administrator  
Agriculture Sciences Division  
Montana Department of Agriculture  
P.O. Box 200201  
Helena, MT 59620-0201

February 10, 1999

Dear Dr. Gingery:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 99-039-16n Applicant #: 99-056XRAB  
Received: February 8, 1999 Effective: March 10, 1999  
Institution: Monsanto Recipient: Wheat  
Interstate destination: CO ID MT ND SD WA  
Release destination: CO ID MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori M. Witham

Signature: (b) (6), (b) (7)(C)

Date: 2/16/99

State: Montana





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist  
North Dakota Department of Agriculture  
600 East Boulevard, 6th Floor  
Bismarck, ND 58505-0020

February 10, 1999

Dear Mr. Nelson:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	99-039-16n	Applicant #:	99-056XRAB
Received:	February 8, 1999	Effective:	March 10, 1999
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO ID MT ND SD WA		
Release destination:	CO ID MT ND SD WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (e) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

**(b) (6), (b) (7)(C)**

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.  
 State DOES NOT CONCUR and offers the following reasons:  
 Name of State official: DAVID R NELSON  
 Signature: **(b) (6), (b) (7)(C)**  
 Date: 2-12-99  
 State: ND

2/12/99





United States Department of Agriculture

Animal and Plant Health Inspection Service

4700 River Road Riverdale, MO 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 10, 1999

Dear Mr. Fridley:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ap number 99-039-16n Applicant #: 99-056XRAB
Received: February 8, 1999 Effective: March 10, 1999
Institution: Monsanto Recipient: Wheat
Interstate destination: CO ID MT ND SD WA
Release destination: CO ID MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations Branch
Biotechnology Evaluations
Biotechnology Scientific Services
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Brownsville, TX



STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 2/12/99

State: South Dakota





United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection Service

4700 River Road  
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager  
Laboratory Services Division  
Washington Department of Agriculture  
1111 Washington Street  
Olympia, WA 98504-2560

February 10, 1999

Dear Mr. Wessels:

Enclosed is notification 99-039-16n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 99-039-16n Applicant #: 99-056XRAB  
Received: February 8, 1999 Effective: March 10, 1999  
Institution: Monsanto Recipient: Wheat  
Interstate destination: CO ID MT ND SD WA  
Release destination: CO ID MT ND SD WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations Branch  
Biotechnology Evaluations  
Biotechnology Scientific Services  
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 2/12/99

State: WA

2/16/99



February 22, 1999

(b) (6), (b) (7)(C)

Monsanto Company  
700 Chesterfield Village Pkwy N  
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3 (c), effective on or after March 10, 1999.

**Interstate movement and Release**

**Notification no. 99-039-16n (99-056XRAB)**

**Regulated article - Wheat**

**Destinations - Colorado, Idaho, Montana, North Dakota, South Dakota, Washington**

You must comply with the performance standards as stated in 7 CFR 340.3 (c). In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

E. Dianne Hatmaker, Chief  
Biotechnology Program Operations  
Scientific Services  
Plant Protection and Quarantine

Enclosure

cc:

M. Yergert, Colorado Dept. of Agric., Lakewood, CO  
R. Vega, Idaho Dept. of Agric., Boise, ID  
G. Gingery, Montana Dept. of Agric., Helena, MT  
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND  
K. Fridley, South Dakota Dept. of Agric., Pierre, SD  
T. Wessels, Washington Dept. of Agric., Olympia, WA  
R. Stoaks, PPQ, WR, Sacramento, CA  
D. DeWeese, PPQ, SCR, Brownsville, TX

File number 99-039-16n

OR120018\_BR\_012394

---

Lotus cc:Mail For: (b) (6), (b) (7)(C)

---

Author: (b) (6), (b) (7)(C)  
Date: 2/5/99 2:58 PM  
Priority: Normal  
TO: (b) (6), (b) (7)(C)  
Subject: Re[3]: Notification Approval

----- Message Contents -----

(b) (4)

Reply Separator

Subject: Re[2]: Notification Approval  
Author: (b) (6), (b) (7)(C)  
Date: 02/05/1999 1:31 PM

(b) (6), (b) (7)(C)

I forgot to ask, what is the person's name in Tennessee that will be receiving the seed?

(b) (6), (b) (7)(C)

Reply Separator

Subject: Re: Notification Approval  
Author: (b) (6), (b) (7)(C)  
Date: 2/5/99 8:08 AM

(b) (6), (b) (7)(C)

This should be sent to

(b) (4)

(b) (6), (b) (7)(C)

Reply Separator

Subject: Notification Approval  
Author: (b) (6), (b) (7)(C)  
Date: 02/04/1999 7:42 PM

(b) (6), (b) (7)(C)

Who is the person at (b) (4) that should receive a compliance packet to ship PV-GHBK11 to the (b) (4) TN?

Thanks,

(b) (6), (b) (7)(C)

1999 Wheat Field Test Report  
USDA # 99-039-16n Monsanto # 99-056XRAB

(b) (6), (b) (7)(C)

December 12, 2000

Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
(b) (4)	Weld	CO
(b) (4)	Canyon	ID (Not Planted)
(b) (4)	Pondera	MT
(b) (4)	Cass	ND
(b) (4)	Ward	ND (Not Planted)
(b) (4)	Roberts	SD (Not Planted)
(b) (4)	Whitman	WA
(b) (4)	Walla Walla	WA

Weld County, CO

Planting Date: March 29, 1999

Harvest Date/ Destruct: June 23, 26, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

(b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

(b) (4)

Monitoring for Volunteer Plants: (b) (4)

(b) (4)

**Pondera County, MT**

Planting Date: April 20, 1999

Harvest Date/Destruct: August 24, 1999

Vector Constructs/Line Numbers Planted:

(b) (4)

Purpose of Field Trial:

(b) (4)

Field Monitoring for Disease Susceptibility:

(b) (4)

Field Monitoring for Insect Susceptibility:

(b) (4)

Field Monitoring for Plant Growth Characteristics:

(b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

Method of Devitilization or Final Disposition of Plot area after Harvest:

(b) (4)

**Cass County, ND**

Planting Date: May 26, 1999

Harvest Date/ Destruct: September 29, 1999

Vector Constructs/Line Numbers Planted:

(b) (4)

Purpose of Field Trial:

(b) (4)

Field Monitoring for Disease Susceptibility:

(b) (4)

Field Monitoring for Insect Susceptibility:

(b) (4)

Field Monitoring for Plant Growth Characteristics:

(b) (4)

Field Monitoring for Weediness Characteristics:

(b) (4)

Monitoring for Volunteer Plants

(b) (4)

Whitman County, WA

Planting Date: April 16, 1999

Destruct/Harvest: September 3, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

(b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

(b) (4)

Method of Devitilization or Final Disposition of Plot area after Harvest: (b) (4)

(b) (4)

Monitoring for Volunteer Plants: (b) (4)

(b) (4)

Walla Walla, WA

Planting Date: April 14, 1999

Harvest Date/ Destruct : August 16, 1999

Vector Constructs/Line Numbers Planted: (b) (4)

(b) (4)

Purpose of trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring for Weediness Characteristics: (b) (4)

(b) (4)