EPA REGISTRATION NUMBER 71693-1 – VOLUME 1

DP BARCODE: D286705

CASE: 062458 DATA PACKAGE RECORD DATE: 02/12/03
SUBMISSION: S624885 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 100 NC-FOOD/FEED USE
CHEMICALS: 006456 Aspergillus flavus 36 colonized wheat seed 0.0000%

ID#: 071693-R Aspergillus Flavus AF36
COMPANY: 071693 ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL
PM TEAM REVIEWER: SHANAZ BACCHUS 703-308-8097 ROOM: CS1 5TH FL
RECEIVED DATE: 11/07/02 DUE OUT DATE: 05/16/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 286705 EXPEDITE: N DATE SENT: 11/07/02 DATE RET.: / /
CHEMICAL: 006456 Aspergillus flavus 36 colonized wheat seed
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : BPPD	11/07/02	/ /
BRAN: BPPD-IO	11/07/02	/ /
SECT: IO	11/07/02	/ /
REVR : CETSITTY	11/07/02	/ /
CONTR: OAK RIDGE	12/10/02	/ /

ADMIN DUE DATE: 03/07/03
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the following for use of Aspergillus flavus atoxigenic strain AF36 for use on cotton to displace the toxigenic strain.
457981-01: Acute pulmonary tox/path in rat. This study was discontinued because of the adverse effects of Tween. The other 2 studies were conducted to replace this study.
457391-01 is an interim report of the next study for acute pulmonary tox/path effects of AF36 in rats.
457982-01: Acute pulmonary tox/path in rat (final study).
Consider the last 2 studies together when assigning a tox category to the active ingredient.
Also review the next submission 457391-04 which reports on hypersensitivity incidents.
If you have any questions, do not hesitate to call me on 703-308-8097
Thanks
Shanaz Bacchus

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

DP BARCODE: D286708

CASE: 062458 DATA PACKAGE RECORD DATE: 02/13/03
SUBMISSION: S624888 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 152 PROP TEST PROT-NEW BIOL
CHEMICALS: 006456 Aspergillus flavus 36 colonized wheat seed 0.0000%

ID#: 071693-R Aspergillus Flavus AF36
COMPANY: 071693 ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL
PM TEAM REVIEWER: SHANAZ BACCHUS 703-308-8097 ROOM: CS1 5TH FL
RECEIVED DATE: 11/06/02 DUE OUT DATE: 04/05/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 286708 EXPEDITE: N DATE SENT: 11/07/02 DATE RET.: / /
CHEMICAL: 006456 Aspergillus flavus 36 colonized wheat seed
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 02/20/03
DIV : BPPD	11/07/02	/ /	NEGOT DATE: / /
BRAN: BPPD-IO	11/07/02	/ /	PROJ DATE: / /
SECT: IO	11/07/02	/ /	
REVR : GTOMIMAT	02/13/03	/ /	
CONTR: OAK RIDGE	12/10/02	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the following for use of Aspergillus flavus, atoxigenic strain AF36 on cotton in AZ and TX.
457981-01 Tox/path to bobwhite quail
457391-02 Honey bee study of AF36 on cotton
457391-03 AF36 non-target submission to demonstrate that plovers are not in the treatment areas.
Include any adverse effects observed in the trials in your reports.
If you have any questions, do not hesitate to email me at bacchus.shanaz@epa.gov
Thanks

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

P. Hutton

BPPD PRAT ACTION CODING FORM

PM 90: Janet Andersen

REGISTRANT/COMPANY NAME: IR4

Fast Track: Yes☐ No☐
Reviewer BACCHUS
Assigned by POH

EPA REG./FILE SYMBOL ~~2F6497~~

ACTION CODE ~~201~~

8E 5001

[Note: If Fast Track, you may need to change Reviewer's Name in PRAT.]

(New A.I/EUP'S/Tolerances: Yes☐ No☐)

DATE OF APPLICATION 8/13/02

EPA RECEIVED DATE 8/14/02

Need PC code

BPPD RECEIVED DATE 8/27/02

Take to Teresa Downs on Thu 8/21693-R

SUBMISSION BARCODE _____

ASSIGNED IN PRAT: Yes☐ No☒

COMPLETED BY T. Brenner DATE 9/16/02

LOGGED IN BRATS: Yes☒ No☐ DATE 9-17-02 COMPLETED BY [illegible]

RAL RECEIVED _____ DATE _____
(RAL initials)

FINAL ACTION

RESPONSE CODE: _____

RESPONSE DATE: _____

MOS: _____ (1) Cite All
_____ (4) Not Applicable
_____ (8) Selective

CRP	Yes☐	No☐
Restricted Use:	Yes☐	No☐
Manufacturing Use	Yes☐	No☐
Exclusive Use:	Yes☐	No☐

BPPD

This an ACCEPTED submission

This is a PARTIALLY ACCEPTED/COMPLETELY REJECTED submission

AUG 26 2002

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

INTERREGIONAL RESEARCH PROJECT NO. 4
TECHNOLOGY CENTRE OF N.J.
681 U.S. HIGHWAY #1 SOUTH
NORTH BRUNSWICK, NJ 089023390

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 08/14/02. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents. If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below. These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels. The rejected studies and their deficiencies are described below.

Rejected study [02] :

A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40 CFR160 is required for all studies (except range finding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

* Judging from the pagination of the study, pages. 87 + 95 . were omitted from the submitted copy.

Rejected study [04] :

A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40 CFR160 is required for all studies (except range finding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

Interregional Research Project No. 4
Center for Minor Crop Pest Management

FAX

From: Michael Braverman

To: Shanaz Bachus

FAX: (703) 308-7026

Date: 9/20/02

Number of pages including cover page? ~~4~~ 5

In response to the 86-5 compliance letter the following are attached:

Vol 2 of 7 pg 3
Vol 4 of 7 pg 3
} with Peter Cottys signature as the Sponsor and Submitter (Note: Original signature is archived at IR-4 Headquarters as per GLPs)

Vol 2 of 7 Missing pages 87 and 95

Thanks, Michael Braverman

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

Interregional Research Project No. 4
Center for Minor Crop Pest Management

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Number of pages including cover page? ~~4~~ 5

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Vol 2 of 7 Missing pages 87 and 95

Thanks, Michael Braverman

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

The study described in this report was conducted in compliance with the following Good Laboratory Practice standards and, with the exceptions noted below, I consider the data generated to be valid.

The UK Good Laboratory Practice Regulations 1999 (Statutory Instrument No 3106).

OECD Principles of Good Laboratory Practice (as revised in 1997), ENV/MC/CHEM(98)17.

EC Commission Directive 1999/11/EC of 8 March 1999 (Official Journal No L 77/8).

Information regarding test substance characterisation, namely batch/lot number and expiry date, was not made available to Huntingdon Life Sciences as required for compliance with Good Laboratory Practice Standards given above.

Chemical analysis of formulated test articles for determination of stability and homogeneity was not undertaken for this study.

.....Blanchard.....

Emma L. Blanchard, B.Sc. (Hons.),
Study Director,
Huntingdon Life Sciences Ltd.

..18..April..2002.....
Date

COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

The study described in this report was conducted in compliance with the following Good Laboratory Practice standards and I consider the data generated to be valid.

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M Rodgers

Matthew H. Rodgers, B.Sc. (Hons.),
Study Director,
Huntingdon Life Sciences Ltd.

11 April 2002
Date

Rejected

(02)

Studies

Rejected

(04)

Studies

Interregional Research Project No. 4
Center for Minor Crop Pest Management

FAX

From: Michael Braverman

To: Shanaz Bachus

FAX: (703) 308-7026

Date: 9/20/02

Number of pages including cover page? 5

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} with Peter Cottys signature as the Sponsor and Submitter (Note: Original signature is archived at IR-4 Headquarters as per GLPs)

Vol 2 of 7 Missing pages 87 and 95

Thanks, Michael Braverman

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

Interregional Research Project No. 4
Center for Minor Crop Pest Management

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To: Shanaz Bachus

FAX: (703) 308-7026

Date: 9/20/02

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Thanks, Michael Braverman

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY RUTGERS

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Emma L. Blanchard, B.Sc. (Hons.),
Study Director,
Huntingdon Life Sciences Ltd.

..15..April..2002.....
Date

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M Rodgers
.....
Matthew H. Rodgers, B.Sc. (Hons.),
Study Director,
Huntingdon Life Sciences Ltd.

11 April 2002
.....
Date

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M Rodgers

Matthew H. Rodgers, B.Sc. (Hons.),
Study Director,
Huntingdon Life Sciences Ltd.

11 April 2002
Date

DP BARCODE: D286708

CASE: 062458 DATA PACKAGE RECORD DATE: 11/07/02
SUBMISSION: S624888 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 152 PROP TEST PROT-NEW BIOL
CHEMICALS: 006456 Aspergillus flavus 36 colonized wheat seed 0.0000%

ID#: 071693-R Aspergillus Flavus AF36
COMPANY: 071693 ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL
PM TEAM REVIEWER: SHANAZ BACCHUS 703-308-8097 ROOM: CS1 5TH FL
RECEIVED DATE: 11/06/02 DUE OUT DATE: 04/05/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 286708 EXPEDITE: N DATE SENT: 11/07/02 DATE RET.: / /
CHEMICAL: 006456 Aspergillus flavus 36 colonized wheat seed
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 02/20/03
DIV : BPPD	/ /	/ /	NEGOT DATE: / /
BRAN: BPPD-IO	/ /	/ /	PROJ DATE: / /
SECT: IO	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

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Include any adverse effects observed in the trials in your reports.
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Thanks

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

Need 10 | 1 acute pulm. = final

2, 3, 7

hypersecret

Tween interim

acute pulm

DP BARCODE: D286705

CASE: 062458 DATA PACKAGE RECORD DATE: 11/07/02
SUBMISSION: S624885 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

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DP BARCODE: 286705 EXPEDITE: N DATE SENT: 11/07/02 DATE RET.: / /
CHEMICAL: 006456 Aspergillus flavus 36 colonized wheat seed
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 03/07/03
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BRAN: BPPD-IO	/ /	/ /	PROJ DATE: / /
SECT: IO	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

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* * * DATA PACKAGE EVALUATION * * *

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DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

DP BARCODE: D286705

CASE: 062458 DATA PACKAGE RECORD DATE: 11/07/02
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DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 03/07/03
DIV : BPPD	/ /	/ /	NEGOT DATE: / /
BRAN: BPPD-IO	/ /	/ /	PROJ DATE: / /
SECT: IO	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

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Shanaz Bacchus

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* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

NOV 07 2002

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

SOUTHERN REGIONAL RESEARCH CENTER
AGRICULTURAL RESEARCH SERVICES
P.O. BOX 19687
NEW ORLEANS, LA 70179

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 09/17/02. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Post-it® Fax Note 7671	Date 11/12/02	# of pages ▶ 5
To Mike Bowerman	From Shanaz Bacchus	
Co./Dept. USDA IR-4	Co. EPA/BPPD	
Phone # 732-932-9575 x610	Phone # 703-308-8097	
Fax # 732-932-8481	Fax # 703-308-7026	

8EJ001
~~2EJ571~~

Interregional Research Project No. 4
Center for Minor Crop Pest Management

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk (IR4)
266A Crystal Mall No. 2
1921 Jefferson Davis Highway
Arlington, VA 22202

BIOPESTICIDE
PROPOSAL

Sept. 12, 2002

RE: Aspergillus flavus AF-36/Tolerance Exemption for cotton
RAL: Shanaz Bacchus (703)308-8097

Dear Janet:

The undersigned, Dr. Michael Braverman, Interregional Research Project No. 4, The Technology Centre of New Jersey, 681 U.S. Highway #1 South, North Brunswick, New Jersey 08902-3390, on behalf of the IR-4 Project submit this petition pursuant to Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the microbial biopesticide, Aspergillus flavus AF-36.

List of Studies Submitted in Support of Proposed Exemption
from the Requirements of a Tolerance for Aspergillus flavus AF-36.

Volume No. and Title

45798201 Volume 1- Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat

Note: Although this volume is being submitted individually, it is the third volume pertaining to studies on ASPERGILLUS FLAVUS AF36 ACUTE PULMONARY TOXICITY AND PATHOGENICITY TO THE RAT.

In a previous submission (August 12, 2002) two volumes (Volume 2 of 7 and Volume 4 of 7) were submitted but no MRID numbers have been assigned yet.

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

Janet Andersen (con't)

List of Supplemental Information Submitted in Support of this Petition:

1. Notice of Filing*
2. Letter of Authorization

* Notice of Filing has already been provided electronically , in Word Perfect format.

Yours very truly,

Michael Bruneman

Interregional Research Project No. 4
Petitioner

Per_____
IR-4 Project Coordinator
IR-4 Project
Rutgers, The State University of New Jersey
The Technology Centre of New Jersey
681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390

CC; Peter Cotty, Larry Antilla

457981-00

Interregional Research Project No. 4
Center for Minor Crop Pest Management

August 12, 2002

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk (IR4)
266A Crystal Mall No. 2
1921 Jefferson Davis Highway
Arlington, VA 22202

BIOPESTICIDE
PROPOSAL

8E5001
~~2E6497~~

RE: Aspergillus flavus AF-36/Tolerance Exemption for cotton
RAL: Shanaz Bacchus (703)308-8097

Dear Janet:

The undersigned, Dr. W.L. Biehn, Interregional Research Project No. 4, The Technology Centre of New Jersey, 681 U.S. Highway #1 South, North Brunswick, New Jersey 08902-3390, on behalf of the IR-4 Project submit this petition pursuant to Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the microbial biopesticide, Aspergillus flavus AF-36.

List of Studies Submitted in Support of Proposed Exemption
from the Requirements of a Tolerance for Aspergillus flavus AF-36.

Volume No. and Title

Volume 1- ~~Petition Proposing~~ An Exemption from the Requirement of a Tolerance For Sorbitol Octanoate for use in All Food Crops AF36 ADMIN

Volume 2 - Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat 45798101

Volume 3 - Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat -Interim Report. 45739101

Volume 4- Aspergillus flavus isolate AF 36 - Toxicity/ Pathogenicity to the Bob White Quail Avian Inhalation Test Tier 1 45798102

Volume 5 - Honey bee Field Study of Aspergillus flavus AF36 in Cotton 45739102

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

Janet Andersen (con't)

Volume 6 Aspergillus flavus isolate AF36 Non-target Organism and Environmental Safety Information 45739103

Volume 7 - Aspergillus flavus isolate AF 36 - Hypersensitivity Incidents Amendment No. 1 to MRID 43972402, Amendment No. 2 to MRID 43763404 45739104

List of Supplemental Information Submitted in Support of this Petition:

1. Notice of Filing*
2. Letter of Authorization

* Notice of Filing is also being provided electronically , in Word Perfect format, under separate cover.

Yours very truly,

Michael Braverman

Interregional Research Project No. 4
Petitioner

Per_____
IR-4 Project Coordinator
IR-4 Project
Rutgers, The State University of New Jersey
The Technology Centre of New Jersey
681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390

Is your RETURN ADDRESS completed on the reverse side?

SENDER:

- Complete items 1 and/or 2 for additional services.
- Complete items 3, and 4a & b.
- Print your name and address on the reverse of this form so that we can return this card to you.
- Attach this form to the front of the mailpiece, or on the back if space does not permit.
- Write "Return Receipt Requested" on the mailpiece below the article number.
- The Return Receipt will show to whom the article was delivered and the date delivered.

I also wish to receive the following services (for an extra fee):

1. ☐ Addressee's Address
2. ☐ Restricted Delivery

Consult postmaster for fee.

3. Article Addressed to:

DR. Bill Bichu
Technology Center of New Jersey
Interregional Research Project No. 4
681 U.S. Highway #1 South (R-4)
North Brunswick, NJ
08902-3390

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PS Form 3811, December 1991 ★U.S. GPO: 1993—352-714 **DOMESTIC RETURN RECEIPT**

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Shanaz Bacchus (951C)
1200 Pennsylvania Ave N.W
Washington, DC
20460

BPPD PRAT ACTION CODING FORM

PM 90: Janet Andersen

REVIEWER: BACCHUS
(ASSIGNED BY: Pott)

EPA REG./FILE SYMBOL ? 71693-R

ACTION CODE 200

SUBMISSION BARCODE

NOF on Disk

Date on Application 7-30-98

EPA Received Date 8-3-98

PM Received Date 8-4-98

Assigned in PRAT YES ____ NO ✓ No TC [illegible]

Completed by: S. Diana Hudson Date 8-11-98

[illegible]

FINAL ACTION

Response Code ____

Response Date: / /

MOS: ____ (1) Cite-All

____ (4) Not Applicable

____ (8) Selective

CRP: Yes ____ No ____

Restricted Use: Yes ____ No ____

Manufacturing Use: Yes ____ No ____

Exclusive Use: Yes ____ No ____

RECEIVED
AUG 4 1998
OPP/BPPD

Interregional Research Project No. 4
Center for Minor Crop Pest Management

7/30/98

To: Shanaz Bacchus
From: Bill Biehn
RE: NOF on Diskette for Aspergillus flavus AF36 on Cotton / Tolerance Exemption

Attached is the NOF on diskette in Word Perfect 6.1 Format to support the Section 3 Registration.

The NOF has been revised slightly.

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932 8481

Interregional Research Project No. 4
Center for Minor Crop Pest Management

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk
Office of Pesticide Programs - 7504C
U. S. Environmental Protection Agency
401 M. Street (SW)
Washington, DC 20460-0001

JUN 25 1998

RE: Aspergillus flavus isolate AF36 Tolerance Exemption for Cotton

Dear Dr. Andersen:

The undersigned, Dr. W.L. Biehn, Interregional Research Project No. 4, State Agricultural Experiment Station, Rutgers University, New Brunswick, New Jersey 08903, on behalf of the IR-4 Project, the United States Department of Agriculture and the Arizona Cotton Research and Protection Council submit this exemption from the requirement of a tolerance petition pursuant to Section 408 (e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the microbial pesticide Aspergillus flavus isolate AF36.

Since this petition is being submitted in conjunction with the IR-4 Program, no fees should be assessed. Furthermore, it is further requested that fees for submitting and reviewing this petition and application be waived as provided by 40 CFR 152.18(c)(2).

List of Studies Submitted in Support of Proposed Exemption from the Requirement of a Tolerance for Aspergillus flavus isolate AF36.

continued .....

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

Dr. Janet Andersen (con't)

Volume No. and Title

Volume 2 - Aspergillus flavus isolate AF36 - Method of Support Information for exemption from the requirement of a tolerance in or on cotton.

Volume 3 - Aspergillus flavus isolate AF 36 - Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 to MRID No. 43763401.

Volume 4 - Aspergillus flavus isolate AF 36 - Analysis of Samples, Certification of Ingredient Limits, Analytical methods for Certified Limits. Amendment No. 2 to MRID No. 43763402.

Volume 5 - Aspergillus flavus isolate AF36 - Safety Information.

Volume 6 - Aspergillus flavus isolate AF36 - Non-target organism and Environmental Safety Information.

Volume 7 - Aspergillus flavus isolate AF36 - Plant Studies - Request for Waiving of the Requirement for Testing.

List of Supplemental Information Submitted in Support of this Petition

1. Notice of Filing* (FQPA Summary)
2. Letter of Authorization

* Notice of Filing is being provided on diskette in Word Perfect 5.1 format under separate cover.

Sincerely,

William L. Biehn

William L. Biehn, Ph.D.
IR-4 Project

WLB:js
cc: Peter Cotty, USDA/ARS
Jane Robens, USDAARS
Larry Antilla, ACRPC
Phil Wakelyn, National Cotton Council

P.S. Volume 7 was previously submitted to EPA under DP Barcode No. D224186 on 8/9/95 in support of a temporary tolerance exemption for Aspergillus flavus isolate AF36 on cotton. Since no MRID Number was previously assigned to this volume entitled Aspergillus flavus isolate AF36 Plant Studies - Request for Waiving of the Requirement for Testing, we are resubmitting this volume and requesting assignment of an MRID number for tracking purposes.

ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
2403 West Huntington, Suite 101,
Tempe, Arizona 85282-3166
(602) 438-0059
(602) 438-0407 - Fax

June 11, 1998

Dr. Janet Anderson
USEPA
BPPD/OPP (7511 W)
401 M Street SW
Washington , D.C. 20460-0001

Subject : FQPA Summary Document for Publishing in the Federal Register as Part of Initial Filing for Aspergillus flavus AF 36/ Letter of Authorization

Dear Dr. Anderson :

The information contained in the Notice of Filing for Aspergillus flavus AF 36 may be published in the Federal Register.

Sincerely,

Larry Antilla
ACRPC,
Staff Director

- -

ENVIRONMENTAL PROTECTION AGENCY

[PF- ;FRL-]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

Action: Notice.

- -

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the exemption of a tolerance for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by the docket control number PF- , must be received on or before *(insert date 30 days after date of publication in the Federal Register).*

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7506C), Information Resources and Services Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to opp-docket@epamail.epa.gov. Follow the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail, Shanaz Bacchus, Regulatory Action Leader, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: 9th floor Crystal Mall No. 2, 1921 Jefferson Davis Highway, Arlington, VA 22202. Telephone No. (703) 308-8097. e-mail: bacchus,shanaz@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section

408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF-] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m. Monday through Friday, excluding legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number (PF-) and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and record keeping requirements.

Dated: _____

_____
Janet Andersen, Director
Biopesticides and Pollution Prevention Division, Office of Pesticide Programs

Summaries of Petition

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

I. Arizona Cotton Research and Protection Council

PP _____
EPA has received a pesticide petition (PP _____) from Interregional Research Project No. 4 (IR-4) on behalf of the USDA and the Arizona Cotton Research and Protection Council, Tempe Office Headquarters, 2403 W. Huntington Dr. #101, Tempe, AZ 85282-3166 proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a, to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for residues of Aspergillus flavus

isolate AF36 in or on cotton. This is a tolerance exemption with regional registration for use in Arizona only. Pursuant to the section 408(d)(2)(A)(i) of the FFDCA, as amended, the Arizona Cotton Research and Protection Council has submitted the following summary of information data, and arguments in support of their pesticide petition.

A. Proposed Use Practices

Aspergillus flavus isolate AF36 is for application to cotton to control aflatoxin producing strains of Aspergillus flavus and thereby reduce aflatoxin contamination of cottonseed. When applied just prior to bloom, Aspergillus flavus isolate AF36, which does not produce aflatoxin, competitively excludes aflatoxin producing A. flavus strains. Sterile wheat seed colonized with A. flavus strain AF36 is applied at 10 pounds per acre. Use will be limited to the state of Arizona.

B. Product Identity/Chemistry

1. The pesticide and corresponding residues are identified as Aspergillus flavus isolate AF36.

2. Aspergillus flavus isolate AF36 is a naturally occurring isolate. Residues of A. flavus on cottonseed at time of harvest (i.e. colony forming units per gram of seed) have been shown to approximate those of naturally occurring levels of A. flavus. A. flavus is widespread in the environment and has been found on essentially all plant material and soil in Arizona.

3. Since the Arizona Cotton Research and Protection Council is proposing to establish an exemption from the requirement of a tolerance without numerical limitation, an analytical method for detecting and measuring levels of the pesticide residue is considered unnecessary.

C. Mammalian Toxicological Profile

An acute oral toxicity study was performed. The oral LD50 of A. flavus AF36 was determined to be greater than 5000 mg/kg rat body weight. No clinical signs were observed during the study and no abnormalities were observed in any of the rats upon necropsy.

Genotoxicity, reproductive and developmental toxicity, subchronic toxicity and chronic toxicity testing were not performed on this microbial pest control agent. This testing is not warranted, since the label will require applicators and other handlers to wear waterproof gloves, a dust/mist filtering respirator MSHA/NIOSH approval prefix TC-21C, coveralls, long sleeved shirt and long pants, and shoes plus socks so exposure should not be a problem.

D. Aggregate Exposure

1. Dietary Exposure. Aspergillus flavus isolate AF36 is a naturally occurring organism, which does not produce aflatoxin and is thus safer than the A. flavus isolates that produce aflatoxin. Proposed uses and application rates will not result in sustained increases in the total population of A. flavus beyond naturally occurring background levels.

2. Food. The proposed use and application rate are unlikely to increase exposure

of humans to A. flavus by dietary means. The proposed use will make cottonseed meal safer because it will significantly reduce the aflatoxin level in cottonseed meal. Cottonseed meal is used as an animal feed for dairy cattle and livestock. Aflatoxin shows up in the milk of dairy cows that are fed cottonseed meal.

3. Drinking Water. Aspergillus flavus isolate AF36 is a naturally occurring organism. Based on the proposed uses and application rates, it is not anticipated that drinking water will provide a route of exposure to residues of Aspergillus flavus.

4. Non-dietary exposure. The potential for non-occupational, non-dietary exposure to the general population is not expected to be significant and is not expected to present any risk of adverse health effects.

E. Cumulative Exposure

Consideration of a common mechanism of toxicity is not appropriate at this time. Furthermore, there is no expectation of cumulative effects with other pesticides.

F. Safety Considerations

Aspergillus flavus isolate AF36 is a naturally occurring organism. This isolate has low toxicity as demonstrated by the acute oral toxicity study in rats. A. flavus is ubiquitous throughout the hot desert valleys in Arizona. Studies have shown that treatment of cotton fields just prior to bloom with sterile wheat seed colonized by A. flavus isolate AF36 at 10 lbs. per acre does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Based on this information, the aggregate exposure to Aspergillus flavus isolate AF36 over a lifetime should not pose an appreciable risk to human health. There is a reasonable certainty that no harm will result from aggregate exposure to A. flavus isolate AF36. Exempting Aspergillus flavus isolate AF36 from the requirement of a tolerance should be considered safe and pose insignificant risk.

G. Existing Tolerances

The registrant is not aware of any existing tolerance exemptions for Aspergillus flavus isolate AF36, other than the temporary tolerance exemption on cotton which expires on May 20, 1999.

JUL 17 1998

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

INTERREGIONAL RESEARCH PROJECT NO. 4
NJ AGRICULTURAL EXPERIMENT STA
P.O. BOX 231
NEW BRUNSWICK, NJ 089030231

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 07/01/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents. If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below. These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels. The rejected studies and their deficiencies are described below.

Rejected study [04] :

If using the EPA Form 8570-4 (Rev. 2-85) Confidential Statement of Formula as data, it should be removed to a confidential attachment as confidential material.

OPTIONAL FORM 99 (7-90) (7/24/98)

FAX TRANSMITTAL # of pages ▸ 3

To Dr William Biehn	From Shanaz Bacchus
Dept./Agency IR-4/USDA	Phone # 703-308-8097
Fax # 732-932-8481	Fax # 703-308-7026

NSN 7540-01-317-7388 5099-101 GENERAL SERVICES ADMINISTRATION

445970-00

Interregional Research Project No. 4
Center for Minor Crop Pest Management

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk
Office of Pesticide Programs - 7504C
U. S. Environmental Protection Agency
401 M. Street (SW)
Washington, DC 20460-0001

JUN 25 1998

RE: Aspergillus flavus isolate AF36 Tolerance Exemption for Cotton

Dear Dr. Andersen:

The undersigned, Dr. W.L. Biehn, Interregional Research Project No. 4, State Agricultural Experiment Station, Rutgers University, New Brunswick, New Jersey 08903, on behalf of the IR-4 Project, the United States Department of Agriculture and the Arizona Cotton Research and Protection Council submit this exemption from the requirement of a tolerance petition pursuant to Section 408 (e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the microbial pesticide Aspergillus flavus isolate AF36.

Since this petition is being submitted in conjunction with the IR-4 Program, no fees should be assessed. Furthermore, it is further requested that fees for submitting and reviewing this petition and application be waived as provided by 40 CFR 152.18(c)(2).

List of Studies Submitted in Support of Proposed Exemption from the Requirement of a Tolerance for Aspergillus flavus isolate AF36.

continued

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY

Dr. Janet Andersen (con't)

Volume No. and Title

Volume 2 - Aspergillus flavus isolate AF36 - Method of Support Information for exemption from the requirement of a tolerance in or on cotton.
ADMIN

Volume 3 - Aspergillus flavus isolate AF 36 - Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 to MRID No. 43763401.
44597001

Volume 4 - Aspergillus flavus isolate AF 36 - Analysis of Samples, Certification of Ingredient Limits, Analytical methods for Certified Limits. Amendment No. 2 to MRID No. 43763402.
Reject (04)

Volume 5 - Aspergillus flavus isolate AF36 - Safety Information.
ADMIN

Volume 6 - Aspergillus flavus isolate AF36 - Non-target organism and Environmental Safety Information.
ADMIN

Volume 7 - Aspergillus flavus isolate AF36 - Plant Studies - Request for Waiving of the Requirement for Testing.
ADMIN

List of Supplemental Information Submitted in Support of this Petition

1. Notice of Filing* (FQPA Summary)
2. Letter of Authorization

* Notice of Filing is being provided on diskette in Word Perfect 5.1 format under separate cover.

Sincerely,

William L. Biehn

William L. Biehn, Ph.D.
IR-4 Project

WLB:js

cc: Peter Cotty, USDA/ARS
Jane Robens, USDAARS
Larry Antilla, ACRPC
Phil Wakelyn, National Cotton Council

P.S. Volume 7 was previously submitted to EPA under DP Barcode No. D224186 on 8/9/95 in support of a temporary tolerance exemption for Aspergillus flavus isolate AF36 on cotton. Since no MRID Number was previously assigned to this volume entitled Aspergillus flavus isolate AF36 Plant Studies - Request for Waiving of the Requirement for Testing, we are resubmitting this volume and requesting assignment of an MRID number for tracking purposes.

732-932-8481

73

JACKETS (Fileroom Document Tracking System) 02/05/99
Requested Jackets Report (New Requests) 13:37:08
LVISSE

Requested by : BACCHUS, SHANAZ Barcode : 020220

Agency : EPA Office : OPPTS Program : OPP
Division : BPPD Branch : MPB Section :

Requested on 02/05/99 at 13:35

Jacket Barcode	Regulatory Case File #	Vol/Total	Location							Status
000397200	5E4575	1 / 1	48	/	B	/	02	/	2	Establishe
000638150	8E5001	1 / 1	50	/	A	/	04	/	3	Pending
000624580	071693-R	1 / 1	38	/	A	/	04	/	2	Pending

Total # of jackets requested : 3

Completed: N Date: 2/5 Time: 1:41

BACCHUS, SHANAZ

CONFIDENTIAL

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC
SUBSTANCES

MAY 14 1999

MEMORANDUM

SUBJECT: BPPD Review of Supplementary Information Submitted by the Southern Regional Research Center/IR-4 to Support an EUP for Use of *Aspergillus flavus* AF36 on Cotton in Arizona.

TO: Shanaz Bacchus (PM-90)
Regulatory Action Leader
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511C)

FROM: Michael T. Watson, Ph.D., Plant Pathologist Michael Watson
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511C)

THROUGH: John L. Kough, Senior Scientist John L. Kough
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511C)

ACTION REQUESTED: To review supplementary information submitted by the Southern Regional Research Center (USDA)/IR-4 to determine if it satisfies deficiencies noted in the previous memorandum (Watson to Bacchus, 3/29/99) to support approval of an EUP for use of *Aspergillus flavus* AF36 on cotton in Arizona.

~~****CONTAINS CONFIDENTIAL BUSINESS INFORMATION****~~

BACKGROUND: Review of the previous application [Submission No.: S547811; ID No.: 069224-EUP-001; DP Barcode: D252699 7 D248824] by the Southern Regional Research Center/IR-4 group, for an extension and expansion of the EUP for use of *Aspergillus flavus* strain AF36 on cotton in Arizona identified several deficiencies. These deficiencies, noted in the previous review (Watson to Bacchus, 3/29/99), included:

> **MRID# 446261-01:** 1) Aflatoxin Production: the protocol only mentions "aflatoxin standards" to be placed on the TLC plates and does not describe exactly what standards will be used. These standards should be identified. Also, the level of detection for aflatoxins is not described. This information should be provided based upon tests using acceptable controls; 2) Identification of *A. flavus* in Final Product: six of thirty-six seeds are removed to vials containing water, and the conidia removed are used for vegetative compatibility analyses and spore producing potential. a) how much water is in each vial?; b) does the amount of water affect the detection of non-vegetatively compatible *A. flavus* (i.e., detection limit)?; c) after sectors have formed on the Rose Bengal Selection Medium, what "second" selection media is used for these sectors?; d) there is no indication in the protocol that spore viability is determined. Does the minimum spore yield of 2.5 billion spores/gram (final product) take into account possible variability in spore viability?

SUPPLEMENTAL DATA:

The following responses were provided by Dr. Peter Cotty (4-7-99) of the Southern Regional Research Center to address the deficiencies noted:

1. Aflatoxin Standards: aflatoxin standards are purchased from commercial suppliers. A mixture of aflatoxins B_1, G_1, B_2 and G_2 are spotted in two spots on each thin-layer chromatography plate. In all cases, 4 ng of aflatoxin B_1 is spotted at each location. All four aflatoxin standards are visible under ultraviolet light and are quantifiable on the developed thin-layer chromatography plates via a scanning fluorescence densitometry. The level of detection of aflatoxin is 1 ppb. Each time aflatoxin production is assessed, both positive and negative controls are used. The positive control is a simultaneous fermentation in the same batch of medium by a known aflatoxin producing strain, AF13 and the negative control is uninoculated fermentation medium.

2. Identification of Fungus in Final Product: a) For vegetative compatibility analysis, the seeds are placed in 2.5 ml sterile water; b) According to Dr. Cotty, the quantity of water in the vial should not influence detection of non-vegetatively compatible strains. The technique performs a plus/minus test to determine if AF36 is the strain colonizing the seed evaluated (i.e., either the strain colonizing the seed is AF36, or it is not); c) The second selection medium is called "MIT", which contains Czapek-Dox broth, 15 g/L $KClO_3$, and 20 g/L

agar, pH 6.5; d) According to Dr. Cotty, the viability of the fungus on the wheat seed is determined and the potential for the fungus colonized wheat seed to produce conidia is determined. These conidia form in the field after application and disperse rapidly after forming. He indicates that they have not observed a lack of viability of *A. flavus* conidia produced on various substrates and have not observed variability in viability of *A. flavus* conidia produced on wheat. Quantification of the spores is done by turbimetry and the spore production is extrapolated from a standard curve that they have developed. The standard curve relates turbidity of spore suspension with colony forming units. Thus, the normal variability in spore viability (if any) is included in the measurement.

DISCUSSION: The supplementary information provided by Dr. Cotty addresses some, but not all of the deficiencies. The primary remaining issue is that of spore viability. Dr. Cotty indicates that "the viability of the fungus on the wheat seed is determined and the potential for the fungus colonized wheat seed to produce conidia is determined". However, there is no indication in the original submission, nor in this letter, to indicate how spore viability is determined. The turbidity of the spore solutions is determined and used to provide consistency, but turbidity is not necessarily an indication of viability. There is no indication if/how the viability of the spores in the suspension is determined. Further description of how spore viability is determined should be provided.

In addition, over the course of the EUP, an attempt should be made to develop another tool/mechanism, other than a plus/minus vegetative compatibility test (e.g. genetic marker), that can be used to differentiate strain AF36 from other *A. flavus* species. This mechanism or marker should be sensitive enough to differentiate and enumerate the population of AF36 in cotton field samples. In other words, the detection limit should provide adequate assurance that the population of AF36, vs other *A. flavus* strains, can routinely and accurately be determined.

RECOMMENDATION:

The supplementary information provided is satisfactory to support issuance of an EUP for application of wheat seed coated with *A. flavus* AF36 to cotton fields in Arizona. However, the issue of spore viability should be addressed with further clarification of techniques used to make the viability determination. In addition, an attempt should be made to develop another detection method to supplement vegetative compatibility for differentiation of AF36 from other strains of *A. flavus* in Arizona cotton fields.

69224-EUP-1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DEC 14 1999

Dr. Bill Biehn
Interregional Research project No. 4 (IR-4)
Technology Center of New Jersey
681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390

Dear Dr. Biehn:

Subject: ***Aspergillus flavus* AF36 on cotton in Arizona**
Experimental Use Permit Yearly report (69224-EUP-1)
Section 3 Registration Requirements

Enclosed are a letter from Dr. Janet Andersen outlining the data requirements for the yearly report on the Experimental Use Permit and for the proposed Section 3 registration for *Aspergillus flavus* AF36 on cotton in Arizona. The Data Evaluation Reviews (DERs) included provide rationale for the data requirements. These DERs are being sent to Mr. Larry Antilla, the prospective registrant, and to you as a petitioner for the exemption from tolerance for residues of the active ingredient. Also enclosed is an attachment outlining a time frame for the submission of the data required.

If you need more time to submit the data required, do not hesitate to call me on 703-308-8097 to discuss the issues and to firm up other dates for the submissions.

Sincerely,

Shanaz Bacchus
Chemist/Regulatory Action Leader
Biopesticides and Pollution
Prevention Division.

cc: Larry Antilla

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DEC 14 1999

Dr. Bill Biehn
Technology Center of New Jersey
681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390

Dear Dr. Biehn:

Subject: *Aspergillus flavus* AF36 on cotton in Arizona
Experimental Use Permit Yearly Report
Proposed Section 3 Registration

Below are the data required (a) in the yearly report of the extended Experimental Use Permit (EUP) and (b) a description of data required for the Section 3 registration for *Aspergillus flavus* AF36 on cotton in Arizona. These requirements are summarized in bold and a brief discussion of the rationale behind each of the data requirements follows each requirement.

I. Extended EUP Yearly Report

A. Health effects

1. DATA REQUIRED for Quality Assurance - The yearly report for the EUP must include a summary of the analyses for each batch , showing levels of (a) aflatoxin and (b) human pathogen and other contaminant(s) in the batches and notations of the batches destroyed. During the EUP extension, details of the laboratory tests supporting these summarized data reports must be kept in your records and are subject to audit.

Quality Controls (product identity and aflatoxin production): In the yearly report for the EUP, provide summaries of records to demonstrate that:

(a) The fungus present on the wheat seeds is AF36. This identification can be done by vegetative compatibility.

(b) *A. flavus* AF36 has not acquired the ability to produce aflatoxins (i.e., test for aflatoxins). You must include in your records notation of *A. flavus* AF36 batches which were destroyed because of any significant level of aflatoxin produced by that batch. Details of these batch analyses must be maintained in your laboratory or production records and are subject to audit.

Quality Controls (human pathogens and other microbial contaminants): Quality control measures must be identified, reported to the Agency, and implemented to indicate what levels of contaminants are

considered acceptable. This includes human pathogens, as well as other contaminating microbes. Batches of the pesticide containing contaminants above regulatory levels, must be destroyed.

B. Ecological Effects

For a detailed discussion of the ecological data requirements below, see the attached DERs by Dr. Doug Gurian-Sherman. If discussion about the protocols or any other further clarification about field monitoring is needed, feel free to consult with us.

1. DATA REQUIRED - air monitoring of spores: Data for each of two seasons must be included in the annual report of the EUP and submitted in support of the proposed Section 3 registration.

During the EUP, **air monitoring of spores** is required to determine whether total *A. flavus* spore production in treated cotton fields is significantly higher than in untreated fields. Data presented in Volume 1 of the study, completed 12/8/98, suggest that *A. flavus* inoculum production in treated fields is typically not higher than in untreated agricultural fields. However, the studies presented were not designed to determine whether this is true, and therefore air sampling studies of *A. flavus* conidia in treated and untreated fields are required. Reports must include data from July through October of each season. If the genetic marker test is available (see DATA REQUIREMENT 2 for human health effects below) provide data to demonstrate the relative proportions of AF36 to total *A. flavus*. These data are required because pulmonary exposure is an important route for avian aspergillosis infection.

2. DATA REQUIRED - **Propagules in cotton field soil: Collect data to determine the amount of *A. flavus*** propagules in cotton field soil and on the crop at maturity.

Data presented to demonstrate the lack of change in the amount of propagules in cotton field soil one year following treatment, and on the crop at maturity, were sufficient to support the proposed expanded EUP. However, these reports demonstrated a high level of variability. Because this risk assessment relies substantially on exposure data and AF36 is a possible pathogen, the Agency requires analyses of these soil samples, at least for an additional year, to support your application for full Section 3 registration.

II. SECTION 3 REGISTRATION DATA REQUIREMENTS

The following data are required for the Section 3 registration. Some of these requirements are described in detail above under the EUP since they are routine analyses required for record-keeping.

A. Health Effects

1. DATA REQUIRED - During production you must submit summaries of the Quality Assurance reports of all production batches for (a) aflatoxin and (b) human pathogen contaminants and other contaminants and metabolites of toxicological concern. Your report must include notations of the batches of *A. flavus* AF 36 destroyed on the basis of aflatoxin or any other contamination above regulatory levels.

Quality Control: To ensure that production batches are consistent, you must continue to monitor them as required above for the EUP extension. Provided that the manufacturing process remains unchanged, and the production batches meet Agency requirements, frequency of the testing may decrease. The requirement will always remain to destroy batches (lots) containing contaminants of

toxicological concern. Such contaminants include either aflatoxin producing *A. flavus*, or aflatoxin itself, or other human pathogens or microbial contaminants or any other potentially toxic metabolites. Only summaries of these tests must be submitted to the Agency. Details of these data must be available for laboratory audits or other enforcement actions as required under the regulations. If the manufacturing method changes from that used for the EUP, you must submit appropriate product identity, product chemistry, and quality control/assurance data to support the new manufacturing method..

2. DATA REQUIRED - A genetic marker test or other more definitive Quality Assurance procedure is required to distinguish *A. flavus* AF 36 from other *A. flavus* species.

An attempt must be made to develop another tool/mechanism, rather than plus/minus vegetative compatibility to differentiate *Aspergillus flavus* AF36 from other *A. flavus* species. Such a test may be a genetic marker or another mechanism sensitive enough to differentiate and enumerate the population of AF 36 in cotton field samples. In other words, the detection limit should provide adequate assurance that the population of AF 36, versus other *A. flavus* strains can routinely and accurately be determined. For additional information regarding this requirement see Agency memorandum dated May 14, 1999 from Michael T. Watson to Shanaz Bacchus.

3. DATA REQUIRED - Acute pulmonary toxicity/pathogenicity study in appropriate mammalian model.

Acute pulmonary toxicity/pathogenicity in mammals: Because no data have been submitted for the EUP to demonstrate the acute pulmonary toxicity/pathogenicity of *A. flavus* AF36 to mammals, guideline studies conducted in an appropriate mammalian model are required for a Section 3 registration.

B. Ecological Effects

In addition to the air and soil monitoring of spores discussed above, the Agency requires the following ecological effects data to support the Section 3 registration. It is recommended that you use two different species of birds for the avian acute oral and acute pulmonary studies (1 and 2 below). These two data requirements can be discussed with Agency scientists at a teleconference, if necessary.

1. DATA REQUIRED - Based on the observations below, an acute avian oral toxicity/pathogenicity study is required in order to determine the ecological effects of AF36 on avian species to satisfy guideline requirements. These data will be required for the Section 3 registration.

Acute oral toxicity/pathogenicity to birds. Bird census data (MRID 444642-02), submitted in support of the permit, suggest that native bird species are present in cotton fields in Arizona during and after pesticide application. Both studies which present census data (MRID 444642-02 and 444526-15) conclude that red wing blackbirds are the predominant species in cotton fields. However, MRID 444642-02, Table V, demonstrates that many other species are present in cotton fields at frequencies (~15 - 100%) comparable to adjacent native habitat. In addition, MRID 444642-02 reported that a significant proportion of birds were foraging in the fields. MRID 444526-15 demonstrated much lower percentage of foraging, but suggested that this was due to experimental difficulties and that actual percentages were likely to be much higher. MRID 444779-01 has also been reviewed, but the extensive census data of the other two studies are more relevant to risk assessment of the current biopesticide. Therefore, even if the amount of treated wheat applied (10 lb/A) would not be enough to attract birds to cotton fields, birds are present in any case and are likely to find some of the seed. Consequently, an acute avian oral toxicity/pathogenicity study is required.

2. DATA REQUIRED - Avian acute pulmonary toxicity/pathogenicity study in the northern bobwhite quail.

Avian Acute Pulmonary Pathogenicity: *A. flavus* is a known pathogen of birds. Because birds are expected to be present in cotton fields after sporulation of AF36, there is a potential for pulmonary exposure to avian species. An avian acute pulmonary toxicity/pathogenicity study in the northern bobwhite quail is required to ascertain the effects of *A. flavus* AF36 on birds.

3. DATA REQUIRED - Non-target study to demonstrate effects on honey bee.

Non-target bee data: The published literature indicates that several bee species are pollinators of cotton, and may be present in cotton fields at flowering, when AF36 treated wheat would be present. *A. flavus* is known to cause stone brood of honey bees, and therefore hive exposure studies are required. Since preliminary data, discussed above, suggests that exposure is probably not higher for bees in treated than untreated fields, these studies may be performed during the EUP and submitted in support of the Section 3 registration.

The data discussed above must be submitted in the yearly report of the EUP and/or in support of the Section 3 registration as indicated in this letter. A summary of the time frame for the submission of the data is provided in the Attachment (1 page). The proposed time frame indicates that potential Section 3 registration depends on the acceptability of the EUP data. If you have any further questions, do not hesitate to call Shanaz Bacchus at 703-308-8097.

Sincerely,

Janet L. Andersen, Ph.D.
Director
Biopesticides and Pollution
Prevention Division.

cc: Larry Attila
J. Maguire

Summary of data requirements for the EUP yearly report and the proposed Section 3 registration for *A. flavus* AF36 on cotton in Arizona

Data requirements for the EUP yearly report		
Guideline	**Data required**	**Required by**
151-20 through 151-25	Summary analyses of each batch, product identity, levels of aflatoxin and other contaminant analyses	Jan 2000 Nov/Dec 2000
Case by case: Similar to 40 CFR 158.640: Gdln. 93-16	Product performance, Efficacy testing of fungicide, product for control of organisms producing mycotoxins - air and soil monitoring of *A. flavus* spores	Jan 2000 Nov/Dec 2000
Data requirements for Section 3 registration		
Guideline	**Data required**	**Required by**
	Data from EUP yearly report above	Nov/Dec 2000
151-20 through 151-25	Genetic marker test for identification of *A. flavus* AF36; Summary analyses of each batch, product identity, levels of aflatoxin and other contaminant analyses	March 2000 Nov/Dec 2000
154-16	Avian acute oral toxicity/pathogenicity	Nov/Dec 2000
154-17	Avian acute pulmonary toxicity/pathogenicity	Nov/Dec 2000
154-24	Honey bee testing	Nov/Dec 2000

ROUTING AND TRANSMITTAL SLIP

Date 12/6/99

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Phil Hutton	PHH	12/8/99
2. Janet Andersen	KLC	12/10/99
3.		
4.		
5.		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS

A. figures AF36 on cotton
EUP Yearly Report
+
Section 3 data requirements

Shari:
Call Phil Wakelyn
of Cotton Council when
signed so he can get
info from IR-4
TNX - Phil

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions DPPD#858

FROM: (Name, org. symbol, Agency/Post)
Shari

Room No.—Bldg. CM2/9th

Phone No. 308 8097

5041-103

*U.S. Government Printing Office: 1995 — 387-722/20018

OPTIONAL FORM 41 (Rev. 1-94)
Prescribed by GSA

ROUTING AND TRANSMITTAL SLIP

Date 11/30/99

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. Doug Gurian-Sherman	DGS	12/1/99
2. Mike Watson	MW	11-30-99
3. John Kough	JK	12/3/99
4. Gail Tonnmatsu	GT	12/7/99
5. Phil Hutton		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate	X	Signature
	Coordination		Justify		

REMARKS

A. Flavus.

AF36 on Cotton –

Data requirements

– Shan See recommended changes

Doug

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)	Room No.—Bldg.
Shan	CM2-9th Fl
	Phone No. 308-8097

5041-103

*U.S. Government Printing Office: 1995 — 387-722/20018

OPTIONAL FORM 41 (Rev. 1-94)
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* Complete items 1 and/or 2 for additional services.
* Complete items 3, and 4a & b.
* Print your name and address on the reverse of this form so that we can return this card to you.
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I also wish to receive the following services (for an extra fee):

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Consult postmaster for fee.

3. Article Addressed to:

DR BILL BIEHN (IR-4)
TECHNOLOGY CENTER OF NEW JERSEY
INTERREGIONAL RESEARCH PROJ #4
681 US HIGHWAY #1 STA
NORTH BRUNSWICK NJ
08902-3390

4a. Article Number

4b. Service Type

☐ Registered ☐ Insured
☐ Certified ☐ COD
☐ Express Mail ☐ Return Receipt for Merchandise

7. Date of Delivery

12/20/99

5. Signature (Addressee)

8. Addressee's Address (Only if requested and fee is paid)

6. Signature (Agent)

PS Form 3811, December 1991 ★U.S. GPO: 1993—352-714 DOMESTIC RETURN RE

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Shanaz Bacchus
EPA/OPP/BPPD (7511C)
401 M St SW
Washington DC 20460

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3. Article Addressed to:

MR. LARRY ANTILLA
ARIZONA COTTON RESEARCH & PROTECTION COUNCIL
3721 EAST WIER AVENUE
PHOENIX, AZ 85040

4a. Article Number

Z069 410 606

4b. Service Type

☐ Registered ☐ Insured
☐ Certified ☐ COD
☐ Express Mail ☐ Return Receipt for Merchandise

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12-20-99

5. Signature (Addressee)

Charlene R. Deal

6. Signature (Agent)

8. Addressee's Address (Only if requested and fee is paid)

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Shanaz Bacchus (7511C)
EPA/OPP/BPPD
401 M St. SW
Washington DC 20460

ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
3721 East Wier Avenue
Phoenix, Arizona 85040-2933
(602) 438-0059 - Phone
(602) 438-0407 - Fax

FAX TRANSMITTAL FORM

DATE: 5/23/03

TO: Shanaz Bacchus FROM: Larry Antillon

DEPT./AGENCY:

FAX NUMBER: 703-308-7026 TOTAL PAGES: 4

SUBJECT: AF36 Conditional Registration Letters

☐ URGENT ☐ FYI ☐ REPLY ☐ COMMENT ☐ RECYCLE

MESSAGE: Thank you for your help!

LR

FOR MORE INFORMATION CALL: PHONE:

ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
3721 East Wier Avenue
Phoenix, Arizona 85040-2933
(602) 438-0059 - Phone
(602) 438-0407 - Fax

Dennis Szuhay, Acting Chief
Microbial and Plant Incorporated Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 910, Crystal Mall 2
Arlington Virginia, 22202
(703) 308-8260

May 23, 2003

RE: **Pending Section 3 Registration-Aspergillus flavus AF36**
EPA Reg. No. 71693-R; Active Ingredient # 006546
Pending Pesticide Petition # 8E5001
RAL Shanaz Bacchus (703)308-8097

Dear Dennis:

This is in response to your letter dated May 22, 2003 (attached) notifying us about our active ingredient *Aspergillus flavus* AF36 eligiblility for a conditional Section 3(c)7(C) registration on cotton in AZ and TX. We are hereby committing to provide the following data within the time frames you requested as shown below as conditions of registration:

1. Guidelines 151-10 through 151-16 (OPPTS Gdln 885.1300): Product Identity

   Analyses of 5 batches is required at production and must include data relevant to certification of limits, detection, identification, enumeration and rejection limits of metabolites and potential human pathogens (bacterial and fungal) using routine quality control and assurance methods to be implemented for large scale production. Batch analysis must also include viability and storage stability data. All batches containing human pathogens above regulatory levels must be destroyed. A confirmatory method, other than Vegetative Compatibility Group analysis, is required to confirm identity of the active ingredient, *Aspergillus flavus* AF36. Data to remove this condition of registration must be submitted within 2.5 years of the conditional registration. If at any time the formulation, manufacturing process or quality control methods change, you must submit appropriate relevant data to amend the conditional registration of this microbial active ingredient.

Our understanding of "enumeration and rejection limits of metabolites" is that we will continue to analyze for aflatoxin in the working culture by TLC in all batches as already described in MRID 44626101 which is prior to inoculating the wheat. We agree to do the analysis for aflatoxin as a post production analysis only as part of the five batch analysis, but there will not be any post production analysis for aflatoxin as part of the routine quality control procedure.

Similarly, our understanding of "A confirmatory method, other than Vegetative Compatibility Group analysis, is required to confirm identity of the active ingredient, *Aspergillus flavus* AF36" means that we will continue to utilize vegetative compatibility grouping as a test prior to and after production . We agree to use a DNA based confirmatory method only on the 5 batch analysis, but not as part of the routine quality control procedure.

2. Efficacy data are required from a large scale field trial in TX to confirm the bridging of data from Arizona to Texas and to demonstrate that *Aspergillus flavus* AF36 reduces aflatoxin-producing strains of *Aspergillus flavus*

A table clarifying these data requirements is below. Through communication with Shanaz Bacchus, we understand that you already have the appropriate final draft label for stamping. We understand that further data may be required for different formulations and application methods and other use sites, on a case by case basis, if such amendments ensue during this conditional registration.

Data required as a condition of Registration of *Aspergillus flavus* AF36			
Guideline	Title of Study	Data Required	Due Date
885.1300 *151B-12*	*Discussion of Formation of Unintentional Ingredients*	*Formation of unintentional ingredients, human pathogen and metabolite identification and quantification (including aflatoxin quantification).*	*During production of 5 batches or 2.5 years after conditional registration date.*
**885.1400* *151B-13*	*Analysis of Samples*	*5 batch analysis to include viability and storage stability data.*	*During production of 5 batches or 2.5 years after conditional registration date.*
**885.1500* *151B-15*	*Certification of limits*	*Standard data requirement for production batches.*	*During production of 5 batches or 2 years after conditional registration date.*
Non-guideline: required for public health hazard	*Efficacy/Product Performance*	*Efficacy/Product Performance data to demonstrate the reduction of toxigenic strains by A. flavus* AF36 in Texas.	2.5 years after conditional registration date.

Sincerely,

Larry Antilla,
Staff Director
Arizona Cotton Research and Protection Council

CC: Shanaz Bacchus, BPPD, USEPA
Phil Hutton, BPPD, USEPA
Janet Andersen, BPPD, USEPA
Peter Cotty, USDA-ARS
Phil Wakelyn, National Cotton Council

Interregional Research Project No. 4
Center for Minor Crop Pest Management

FAX

From: Michael Braverman

To: Shanaz Bacchus

FAX: (703) 308-7026

Date: 3/7/03

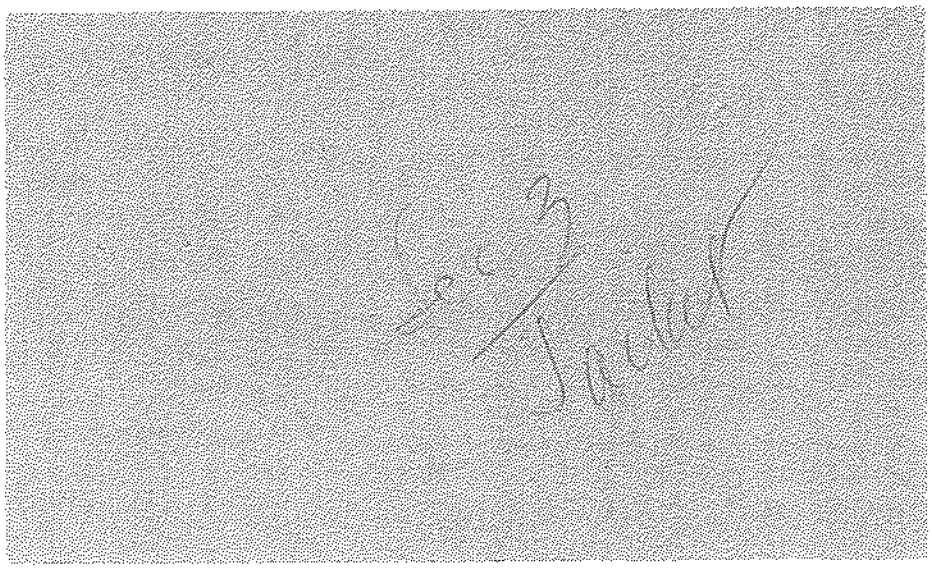
Number of pages including cover page? 9

Shanaz

Please let me know of any corrections/changes you would suggest.

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 71693-R

2. EPA Product Manager: Shanaz Bacchus

3. Proposed Classification: ☑ None ☐ Restricted

4. Company/Product (Name): Aspergillus flavus AF-36

PM#

5. Name and Address of Applicant (Include ZIP Code)
Arizona Cotton Research and Protection Council
3721 E. Wier Avenue
Phoenix, Arizona 85040-2933
☐ Check if this is a new address

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☑ Other - Explain below.

Explanation: Use additional paper if necessary. (For section I and Section II.)
Data waivers for ecological and health effects, efficacy data

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes	☐ Yes	☐ Yes	☐ Metal
☑ No	☑ No	☐ No	☑ Plastic
* Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	☐ Glass
			☐ Paper
			☑ Other (Specify) Bulk boxes, bags

3. Location of Net Contents Information: ☑ Label ☐ Container

4. Size(s) Retail Container: Plastic bag 50lb, Bulk box/bag

5. Location of Label Directions: ☑ On Label

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☑ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name	Title	Telephone No. (Include Area Code)
Larry Antilla	Staff Director	(602)438-0059

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

8. Date Application Received (Stamped)

2. Signature: [signature]

3. Title: Staff Director

4. Typed Name: Larry Antilla

5. Date: 3-5-03

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

White - EPA File Copy (original) Yellow - Applicant Copy

64

Interregional Research Project No. 4
Center for Minor Crop Pest Management

Shanaz Bacchus
Biopesticide and Pollution Prevention Division
Room 910
1921 Jefferson Davis Highway
Arlington, VA 22202
(703)308-8097

March 7, 2003

RE: Aspergillus flavus AF-36 in or on Cottonseed
EPA Reg # 71693-R
PP# 8E5001

Dear Shanaz:

The undersigned, Dr. Michael Braverman, Interregional Research Project No. 4, The Technology Centre of New Jersey, 681 U.S. Highway #1 South, North Brunswick, New Jersey 08902-3390, of the IR-4 Project submit this petition pursuant to Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the microbial pesticide, Aspergillus flavus AF36 on behalf of the Arizona Cotton Research and Protection Council.

List of information Submitted

8570-1 Form

Data Waivers for Health Effects

Data Waivers for Environmental Effects

Research paper in preparation for Phytopathology by Garcia and Cotty "Aflatoxin Contamination of Commercial Cottonseed in South Texas"*

Efficacy data for AF-36 Texas as a public interest document*

* Note: The Aflatoxin and efficacy data are scientific data supplied by Peter Cotty which are intended for journal publication and should be considered Confidential Business Information until the are actually published

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

In regard to your questions concerning the use of AF-36 in Texas in proximity to water and the applicability of the waivers granted for Arizona to include Texas, the target for the product is cotton fields. In both Texas and Arizona, cotton is grown in a monoculture. While the overall environment outside of the fields may differ, cultural practices such as ditch and furrow irrigation make the cotton field environments quite similar for AF-36. Because AF-36 is applied as a granule the product should not drift outside of the cotton field. As shown in the attached article "Aflatoxin Contamination of Commercial Cottonseed in South Texas" there is a very high concentration of aflatoxin already present in cotton fields in the Gulf Coast Region. More specifically, "two sub areas showed recurrent high contamination which are immediately adjacent to the Gulf"(page 11). Like Arizona, a delayed harvest in Texas also results in increased aflatoxin contamination(page 15). It was concluded that the Gulf Coast areas of South Texas are areas that should have similar biological control programs to those used in Arizona(Page 17-18) Aflatoxin production in this area is due to the presence of Aspergillus flavus that produce the toxin. Aspergillus flavus is present on the cotton debris left behind in the field , cotton gin trash placed back on the field which totals about 10,000 pounds of plant debris per acre. Aspergillus flavus is also present in corn grown in the Texas Gulf Coast. The ubiquitous nature of Aspergillus flavus in the region means that all organisms including fish and other aquatic organisms are already exposed to Aspergillus flavus at quantities that vastly exceed the use of the product AF-36. The AF-36 strain is also already found in the soils and plant debris in Texas so there is not any new introduction of the organism. The purpose of applying the product AF-36 is not to increase the amount of Aspergillus population. The purpose is to change the proportion of the Aspergillus community that is composed of the AF-36 strain of Aspergillus. By changing the proportion of the Aspergillus flavus that consists of the AF-36 strain, there is a decrease of the toxin producing strains (such as the S strain). Therefore the use of the product AF-36 would not result in any greater exposure of fish or any other aquatic organism to Aspergillus flavus. In addition since AF-36 reduces aflatoxin production, the use of AF-36 should decrease the amount of aflatoxin exposure to fish and other aquatic organisms.

Yours very truly,

Michael Braverman

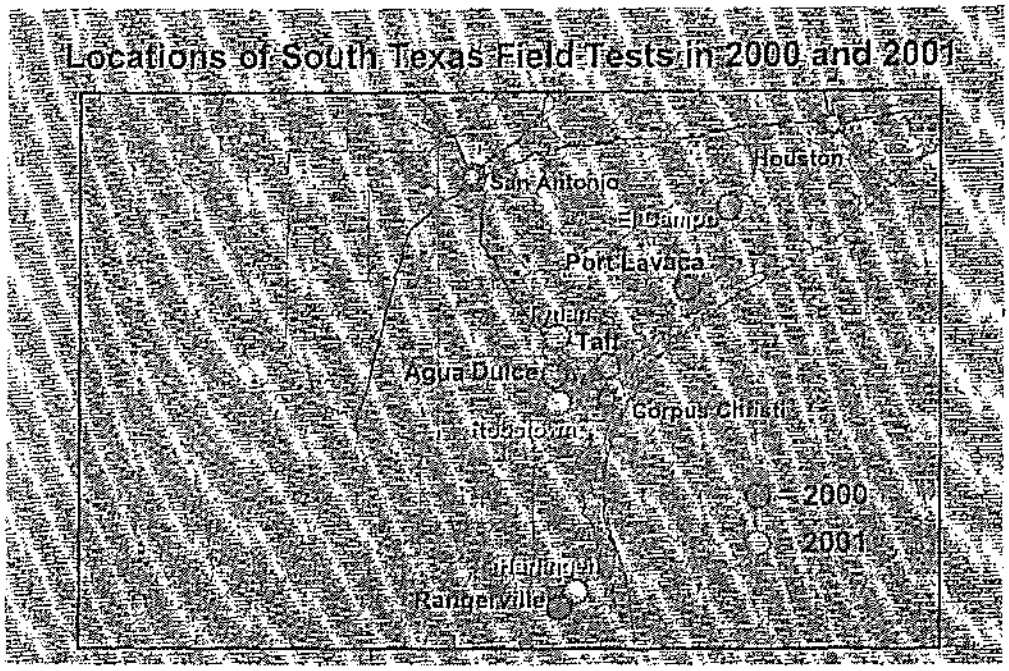
Michael Braverman, Ph.D.
Interregional Research Project No. 4
Petitioner

Per_____
IR-4 Project Coordinator
IR-4 Project
Rutgers, The State University of New Jersey
The Technology Centre of New Jersey
681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390

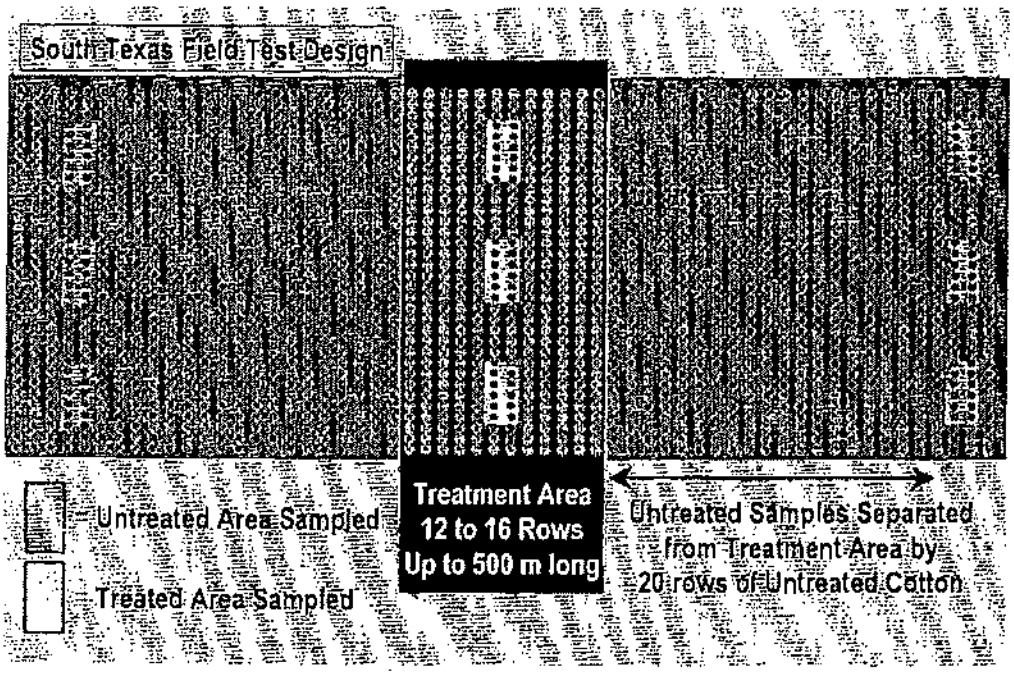
Efficacy of *Aspergillus flavus* AF36 in Texas: Results of Field Tests on the 2000 and 2001 Commercial Cottonseed Crops.

Peter J. Cotty
Research Plant Pathologist
USDA-ARS-SRRC
P.O. Box 19687, New Orleans, LA 70124
504-286-4391

In order to assess efficacy of soil applied *Aspergillus flavus* AF36 in South Texas, field tests were performed in commercial cotton fields at 9 locations throughout South Texas. Tests extended from Rangerville in the Lower Rio Grande Valley area to El Campo in the Upper Coast area.

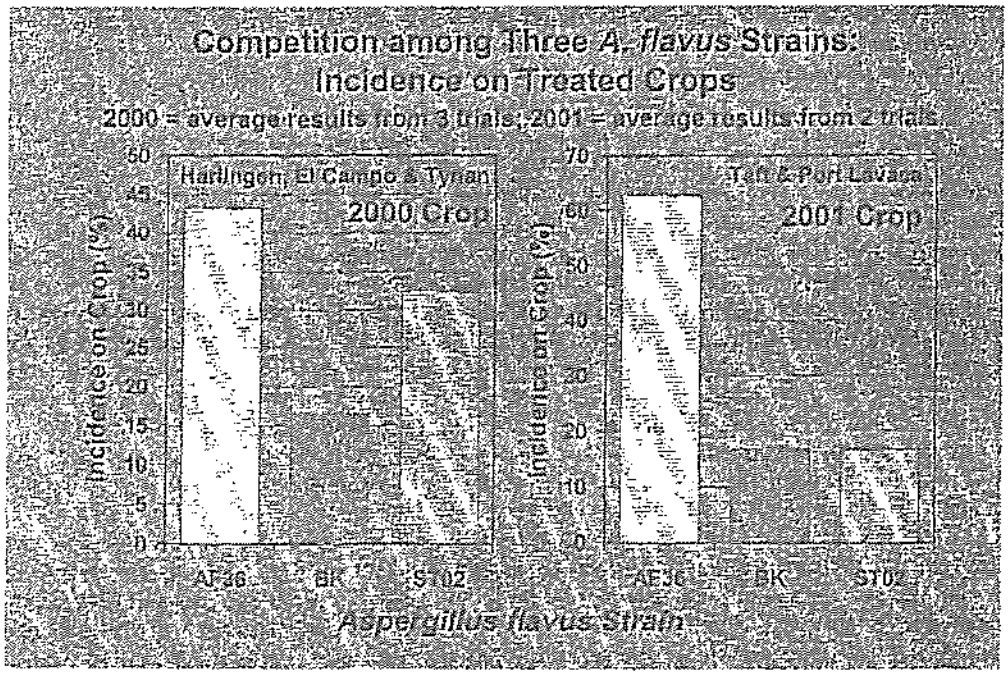


For each test from 0.5 to 1.0 acre of cotton was treated by hand by sprinkling the standard wheat seed formulation of *Aspergillus flavus* AF36 on the soil at the standard rate of 10 lb./acre. In all tests multiple atoxigenic strains of A. flavus native to South Texas were evaluated. All strains were applied to the same area at the same rate in order to observe competition among strains and differences among strains in efficacy. Efficacy of atoxigenic strains at displacing the highly toxigenic S strain and other native strains was assessed by characterizing the communities of fungi associated with the mature crop in both treated areas and in untreated control areas separated from the treated areas by 20 rows of untreated cotton (see field test design below).

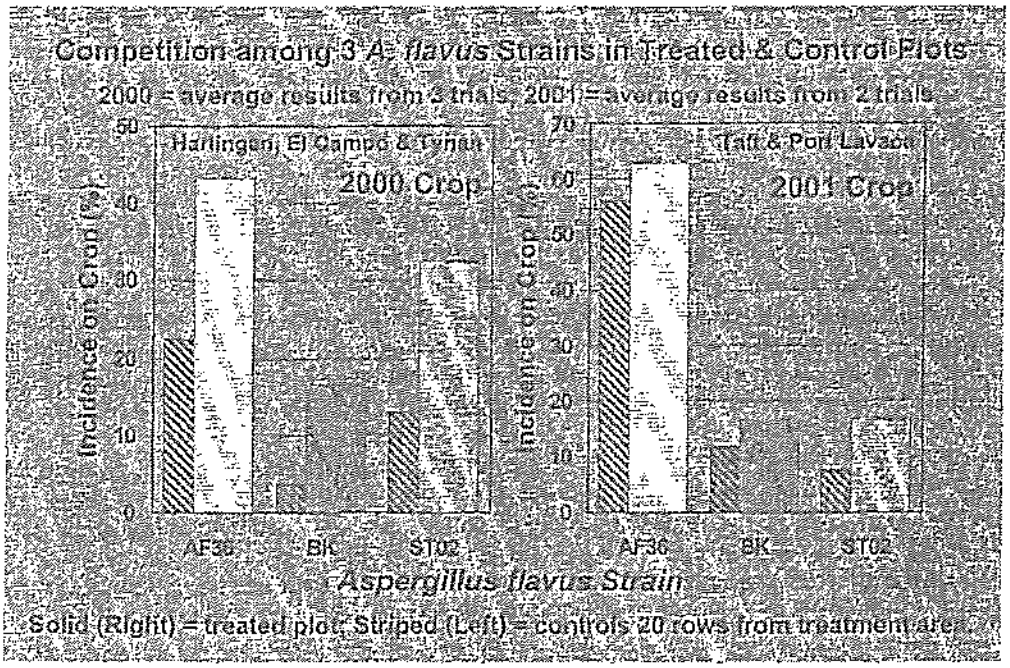


Long-term influences of atoxigenic strains of *A. flavus* have been observed in Arizona. Comparing the communities of fungi resident in the soil just prior to treatment with the community present one year after treatment typically is used to assess this. Such comparisons determine if influences of treatments can be expected to provide a benefit to the environment and crops the second year by reducing the average aflatoxin producing potential of fungi resident in the field across multiple years. The potential for long-term influences of atoxigenic strain applications in South Texas was determined by analyzing the composition of the *A. flavus* communities in the soil of treated plots prior to treatment, with the community structures one year after treatment. Similar comparisons were made contrasting soil in the untreated control plots.

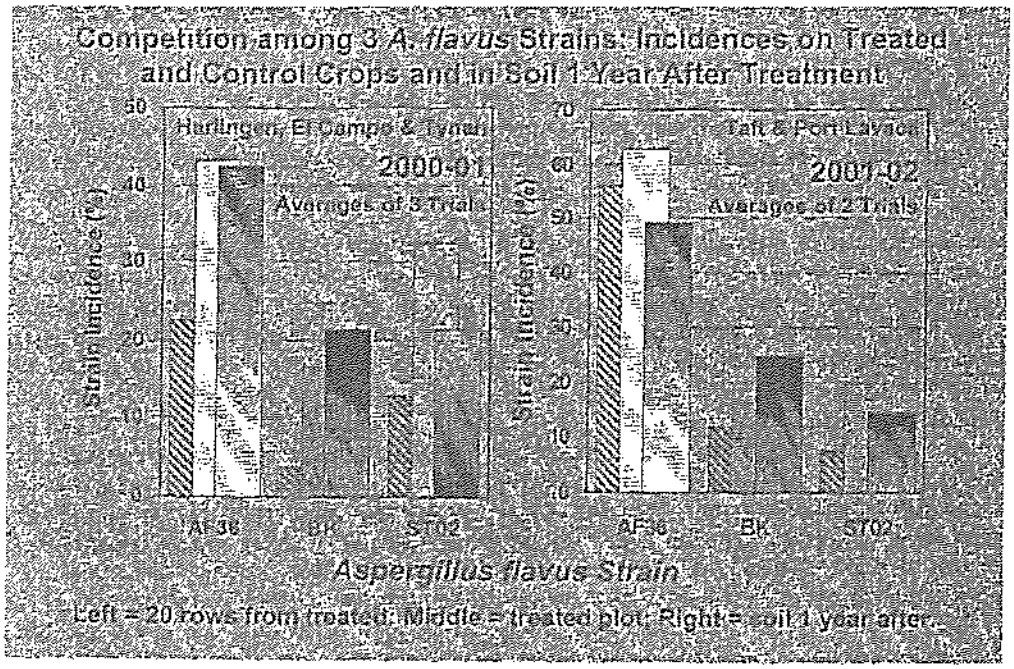
In these studies, three atoxigenic strains (AF36, BK, and ST02) were applied to the treatment area. Incidence of AF36 on treated crops in 2000 and 2001 demonstrate efficacy of Aspergillus flavus AF36 at displacing aflatoxin producers during crop colonization.



Both AF36 and the other two-atoxigenic strains evaluated were effective at spreading from the applied product to the crop and displacing aflatoxin producers during the process. Each strain was applied a single time at 10 pounds per acre. AF36 was the most effective strain in these tests. All strains had efficacy in displacing resident aflatoxin producers.

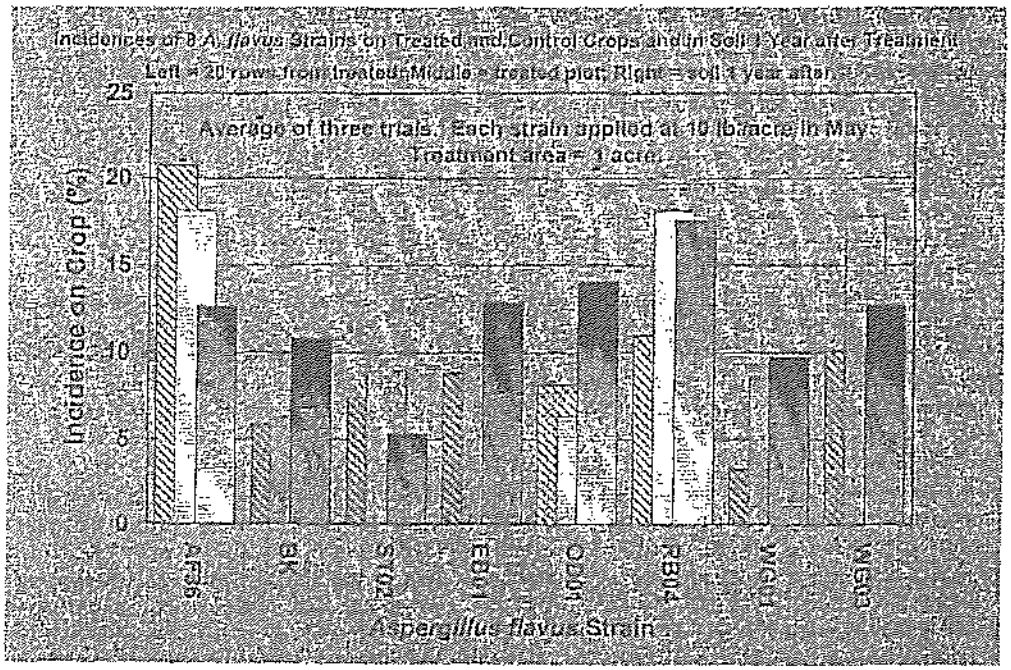


In all tests, AF36 also demonstrated the ability to spread within treated fields across untreated areas. This activity has repeatedly been observed in Arizona and is an aspect of the efficacy of AF36 in displacing aflatoxin producers. The goal of AF36 applications is to modify *A. flavus* communities so that they have a lower potential to produce aflatoxins. The tests in Texas demonstrate great efficacy of AF36 in achieving that goal.



An important aspect of the efficacy of AF36 in Arizona is the ability of applications to make changes to the composition of *A. flavus* communities in soils that are detectable even the season after application. This allows the possibility of inducing long-term reductions in the aflatoxin-producing potential of *A. flavus* communities resident in fields and thus provides the potential to get additive reductions over time. This allows for long-term reductions in the quantity of aflatoxins in crops and in the environment.

Tests performed in Texas in 2000 and 2001 demonstrated excellent efficacy in producing long-term influences of atoxigenic strain applications similar to those seen in Arizona.



Three tests in 2001 were also performed in which 8 atoxigenic strains were compared for efficacy in ability to competitively exclude aflatoxin producers. Aspergillus flavus AF36 demonstrated superior efficacy in these trials as well.

Attachment #2: OPPTS Docket Verification and Certification Form

U. S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES
(OPPTS)
1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460

DOCKET VERIFICATION AND CERTIFICATION FORM

For Internal OPPTS Use Only

Title of Action: Pesticide Product: Registration Application: Aspergillus flavus AF36		
RIN #: 2070-	Docket ID #: OPP-2003-0048	FRL#:
Contact Information:	Name: Shanar Bacchus	Phone: 703-308-8097
Legacy Information:	OPP-2003-0020	

Program Lead's Vertification: I have reviewed the docket and verified the following:

- ☒ All of the documents identified in the attached Docket Index have been submitted to the appropriate Docket Manager for inclusion in the docket identified above.
- ☒ Documents containing copyrighted, CBI or otherwise protected information have been identified to allow for "special" processing by the docket.
- ☒ The material has been assembled in a useable form to support the document being published in the FEDERAL REGISTER.
- ☐ Comments:

Date: 1/30/03	Initials: [signature]	Phone: 703-308-8097

Docket Manager's Verification and Sign-off: I hereby confirm the following:

- ☑ The Docket ID # identified above matches our records.
- ☑ The documents identified in the attached Docket Index have been received by the Docket.
- ☐ The documents have been properly processed for inclusion in EPA Dockets, as appropriate.
- ☐ The documents either already are in the docket or are being process for inclusion in the docket.
- ☐ Comments:

Date: 1/30/03	Signature: [signature] for Kimberly Smith	Phone: 305-5805

Program Lead's Certification: I hereby certify that:

- ☐ I have completed the verification above.
- ☐ I have submitted to the DM all of the documents that I identified needed to be updated, or added to the docket.
- ☐ I have obtained the DM's sign-off.
- ☐ The docket is complete and ready for public release.
- ☐ Comments:

Date: 1/30/03	Signature: [signature]	Phone: 308-8097

FEB 19 2003

Attached You Will Find an Index for Your Docket OPP-2003-0020

TO VIEW THE CONTENTS OF YOUR DOCKET and DOWNLOAD ANY COMMENTS RECEIVED,

LOG ONTO EDOCKET AT:
intranet.epa.gov/edocket
and do a "quick search" for docket - OPP-2003-0020

OPP-2003-0020 Docket Index

Legacy Identifier: OPP-2002-0093
Title: Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food

Displaying 1- 5 of 5 Documents Found

Document ID	Date	Type	Title
OPP-2003-0020-0001	02-14-2003	Federal Register	Aspergillus flavus AF36; Notice of Filing a Pesticide Petition to Establish an Exemption from a Tolerance for a Certain Pesticide Microbial Agent in or on Food
OPP-2003-0020-0002	05-26-1999	Support-Background	Aspergillus Flavus AF36; Pesticides Tolerance Exemption
OPP-2003-0020-0003	05-23-2001	Support-Background	Aspergillus Flavus Af36; Extension of Temporary Exemption from the Requirement of a Tolerance
OPP-2003-0020-0004	07-17-2002	Support-Background	Aspergillus Flavus Af36; Amendment, Temporary exemption from the Requirement of a Tolerance
OPP-2003-0020-0005	12-23-2002	Support-Background	Aspergillus AF36 ai#006456; Pending Section 3 Registration Number 71693-R, Petition 8E5001

FEDEX 8236 0504 5922

RECEIVED 9/12/2000

Interregional Research Project No. 4
Center for Minor Crop Pest Management

September 7, 2000

TO: Ms. Shanaz Bacchus

FROM: William L. Biehn

SUBJECT: Status of Remaining Studies Required for Section 3 Registration of Atoxigenic Aspergillus flavus AF36 for Use on Cotton in Arizona

1. Honey Bee Field Study with Aspergillus flavus AF36 in Cotton (OPPTS Guidelines 850.3040 and 885.4380).

   This study has already been started and should be completed in the near future. The study protocol was reviewed by EPA . Approximate Experimental Termination Date: 9/1/00.

2. Acute Pulmonary Toxicity/Pathogenicity Requirement in Mammals.

   A draft protocol will be sent to EPA for review about 10/01/00. The registrant, Dr. Cotty or IR-4, will obtain three bids from contract labs following protocol approval by EPA. The study will be placed with a contract lab in November.

   The anticipated experimental start date is 2/1/2001, since most contract labs have a waiting period before starting a study. The experimental termination date will be approximately 30 days after the experimental start date.

3. Avian Acute Pulmonary Toxicity/Pathogenicity Requirement in Bobwhite Quail.

   A draft protocol is in preparation and will be available for EPA review 11/01/00. The preferred method of administration is via aerosol inhalation. The registrant or Dr. Cotty or IR-4 will obtain three bids from contract labs following protocol approval by EPA. The study will be placed with a contract lab in December, 2000. It is not possible to estimate the experimental start date at this time.

WLB:js

share\judy\bill\bacchus.wpd

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

FILE NAME: bapply.wpd (9/1/2002)

ENVIRONMENTAL PROTECTION AGENCY

[OPP-~~2002-XXXX; FRL-XXXX-X~~ 2003-0048]

[Note: Get your docket identification (ID) number from the Docket Manager (See OPPTS Interim Guidance for implementing E-Docket for detailed instructions). You get the FRL number from the FRS when the document is sent for editing and coding.]

Pesticide Product; Registration Applications : Aspergillus flavus AF6

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of applications to register pesticide products containing new active ingredients not included in any previously registered products pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Written comments, identified by the docket ID number OPP-2002-XXXX, must be received on or before [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: The Regulatory Action Leader, Biopesticides and Pollution Prevention Division (7511C), listed in the table in this unit:

Regulatory Action Leader	Office address/telephone no.	E-mail address

[Shanaz Bacchus]	[Biopesticides and Pollution Prevention Division (7511C) Office of Pesticide Programs Environmental Protection Agency 1200 Pennsylvania Ave., NW. Washington, DC 20460-0001 telephone number: [703-308-8097]	bacchus.shanaz@epa.gov

SUPPLEMENTARY INFORMATION:

I. General Information

You may be potentially affected by this action if you produce crops; are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2002-XXXX. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal

Attachment #2: OPPTS Docket Verification and Certification Form

U. S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES
(OPPTS)
1200 Pennsylvania Avenue, N.W. , Washington, D.C. 20460

DOCKET VERIFICATION AND CERTIFICATION FORM

For Internal OPPTS Use Only

Title of Action: Pesticide Product: Registration Application. Aspergillus flavus AF36		
RIN #: 2070-	Docket ID #: OPP-2003-0048	FRL#:
Contact Information:	Name: Shanan Bacchus	Phone: 703-308-8097
Legacy Information:	OPP-2003-0020	

Program Lead's Vertification: I have reviewed the docket and verified the following:

- ☒ All of the documents identified in the attached Docket Index have been submitted to the appropriate Docket Manager for inclusion in the docket identified above.
- ☒ Documents containing copyrighted, CBI or otherwise protected information have been identified to allow for "special" processing by the docket.
- ☒ The material has been assembled in a useable form to support the document being published in the FEDERAL REGISTER.
- ☐ Comments:

Date: 1/30/03	Initials: Shanan Bacchus	Phone: 703-308-8097

Docket Manager's Verification and Sign-off: I hereby confirm the following:

- ☑ The Docket ID # identified above matches our records.
- ☑ The documents identified in the attached Docket Index have been received by the Docket.
- ☐ The documents have been properly processed for inclusion in EPA Dockets, as aporopriate.
- ☐ The documents either already are in the docket or are being process for inclusion in the docket.
- ☐ Comments:

Date: 1/30/03	Signature: Wilcher for Kimberly Smith	Phone: 305-5805

Program Lead's Certification: I hereby certify that:

- ☐ I have completed the verification above.
- ☐ I have submitted to the DM all of the documents that I identified needed to be updated, or added to the docket.
- ☐ I have obtained the DM's sign-off.
- ☐ The docket is complete and ready for public release.
- ☐ Comments.

Date: 1/30/03	Signature: Shanan Bacchus	Phone: 308-8097

Kimberly Smith

01/29/03 04:16 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: Confirmation of Docket #OPP-2003-0048

This note is to confirm the docket number(s) that was/were given to you on 1/29
If the Number(s) is/are **CORRECT**, ***please DON'T respond***

OPP-2003-0048

Kimberly Smith/ASRC
Task Order Manager
EPA Office of Pesticide Programs
Public Docket Manager
Phone: 703-305-6434

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U. S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES
(OPPTS)
1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460

DOCKET VERIFICATION AND CERTIFICATION FORM

For Internal OPPTS Use Only

Title of Action: Pesticide Product: Registration Application: Aspergillus flavus AF36		
RIN #: 2070-	Docket ID #: OPP-2003-0048	FRL#:
Contact Information:	Name: Shanaz Bacchus	Phone: 703-308-8097
Legacy Information:	OPP-2003-0020	

Program Lead's Vertification: I have reviewed the docket and verified the following:

- ☒ All of the documents identified in the attached Docket Index have been submitted to the appropriate Docket Manager for inclusion in the docket identified above.
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- ☐ Comments:

Date: 1/30/03	Initials: [signature]	Phone: 703-308-8097

Docket Manager's Verification and Sign-off: I hereby confirm the following:

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Date 1/30/03	Signature: [signature] for Kimberly Smith	Phone: 305-5805

Program Lead's Certification: I hereby certify that:

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- ☐ I have obtained the DM's sign-off.
- ☐ The docket is complete and ready for public release.
- ☐ Comments:

Date: 1/30/03	Signature: [signature]	Phone: 308-8097

71693-R

Docket # 2003-0048 *Aspergillus flavus* AF36 January 29, 2003

Index of documents for docket # 2003-0048:

Pesticide Product; Registration Applications - *Aspergillus flavus* AF36

1. Draft Notice of Receipt of an application: Pesticide Product; Registration Applications - *Aspergillus flavus* AF36. OPP-2003-0048 [7 pages]

2. Draft Notice of Filing a Pesticide Petition to Establish an Exemption from Tolerance for a Certain Microbial Pesticide in or on Food. OPP-2003-0020. 14 pages

3. Release Authorization from IR-4 (Dr. M. Braverman to Shanaz Bacchus, 12/23/02). 8 pages

4. Federal Register Notice: Final Rule - May 26, 1999 (Volume 64, Number 101) Page 28371-28374. Aspergillus flavus AF36; Pesticide Tolerance Exemption. 10 pages

5. Federal Register Notice: Final Rule -May 23, 2001 (Volume 66, Number 100) Page 28383-28386. Aspergillus flavus AF36; Extension of Pesticide Temporary Tolerance Exemption. 8 pages

6. Federal Register Notice: Aspergillus flavus AF36; Amendment, Temporary Exemption From the Requirement of a Tolerance. Final Rule -July 17, 2002 (Volume 67, Number 137)] [Rules and Regulations] [Page 46884-46888]. 6 pages

71693-12

Docket # 2003-0048 *Aspergillus flavus* AF36 January 29, 2003

Index of documents for docket # 2003-0048:

Pesticide Product; Registration Applications - *Aspergillus flavus* AF36

1. Draft Notice of Receipt of an application: Pesticide Product; Registration Applications - *Aspergillus flavus* AF36. OPP-2003-0048 [7 pages]

2. Draft Notice of Filing a Pesticide Petition to Establish an Exemption from Tolerance for a Certain Microbial Pesticide in or on Food. OPP-2003-0020. 14 pages

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4. Federal Register Notice: **Final Rule** - May 26, 1999 (Volume 64, Number 101) Page 28371-28374. Aspergillus flavus AF36; Pesticide Tolerance Exemption. 10 pages

5. Federal Register Notice: **Final Rule** -May 23, 2001 (Volume 66, Number 100) Page 28383-28386. Aspergillus flavus AF36; Extension of Pesticide Temporary Tolerance Exemption. 8 pages

6. Federal Register Notice: Aspergillus flavus AF36; Amendment, Temporary Exemption From the Requirement of a Tolerance. **Final Rule** -July 17, 2002 (Volume 67, Number 137)] [Rules and Regulations] [Page 46884-46888]. 6 pages

FILE NAME: bapply.wpd (9/1/2002)

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0048; FRL-XXXX-X]

[Note: Get your docket identification (ID) number from the Docket Manager (See OPPTS Interim Guidance for implementing E-Docket for detailed instructions). You get the FRL number from the FRS when the document is sent for editing and coding.]

Pesticide Product; Registration Applications - Aspergillus flavus AF36

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of applications to register pesticide products containing new active ingredients not included in any previously registered products pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Written comments, identified by the docket ID number OPP-2003-0048, must be received on or before [*insert date 30 days after date of publication in the* Federal Register].

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: The Regulatory Action Leader, Biopesticides and Pollution Prevention Division (7511C), listed in the table in this unit:

Regulatory Action Leader	Office address/telephone no.	E-mail address

[Shanaz Bacchus]	[Biopesticides and Pollution Prevention Division (7511C) Office of Pesticide Programs Environmental Protection Agency 1200 Pennsylvania Ave., NW. Washington, DC 20460-0001 telephone number: [703-308-8097]	bacchus.shanaz@epa.gov

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- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0048. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall

#2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

[Note: You do not need to cite to a legacy docket here, because E-Dockets does it already. In the case of a rulemaking, you may consult with RCS & OGC, to get the OK to provide such a reference.]

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at http://www.epa.gov/fedrgstr/.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

[Note: If there is a legacy docket for a related document, you need to check with RCS & the DM to see if you must revise this language slightly to reflect that the docket for the document may not be available in EPA Dockets.]

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The

entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at http://www.epa.gov/edocket, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2003-0048. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP-2003-0048. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail

system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency (7502C), 1200 Pennsylvania Ave., NW., Washington, DC, 20460-0001, Attention: Docket ID Number OPP-2003-0048.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA., Attention: Docket ID Number OPP-2003-0048. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI To the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

Note: If you do not anticipate receiving CBI or otherwise protected information, you may omit the preceding section AFTER getting OK from the OGC attorney assigned to your action (or the program regulatory contact).

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the registration activity.

7. Make sure to submit your comments by the deadline in this notice.

8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal **Register** citation.

Note: The preceding section may be omitted for most proposals, but is recommended for major rulemakings.

II. Registration Applications

EPA received applications as follows to register pesticide products containing active ingredients not included in any previously registered products pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of these applications does not imply a decision by the Agency on the applications.

A. Products Containing Active Ingredients not Included in any Previously Registered Products

[File #: 71693-R]

B. [*Aspergillus flavus* AF36]

This notice announces receipt of an application to register a new active ingredient for a naturally occurring microbial pesticide, *Aspergillus flavus* AF36, a non-aflatoxin-producing strain of *Aspergillus flavus*, to reduce aflatoxin contamination on cotton. The application was filed by the Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, Technology Center of New Jersey, 681 U. S. Highway #1 South, North Brunswick, NJ 08902-3390 on behalf of the Arizona Cotton Research and Protection Council, 3721 East Wier Avenue Phoenix, Arizona 85040-2933. *Aspergillus flavus* AF 36 occurs naturally in Arizona and Texas. For details regarding the proposed exemption from tolerance and efficacy data for this active ingredient see docket # OPP-2003-0020.

List of Subjects

Environmental protection, Pesticides and pest.

Dated: _____

_____

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 02-?????? Filed ??-??-02; 8:45 am]
BILLING CODE 6560-50-S

Interregional Research Project No. 4
Center for Minor Crop Pest Management

Shanaz Bacchus
Biopesticides and Pollution Prevention Division
Environmental Protection Agency
ROOM 910 (7511 C)
Crystal Mall No. 2
1921 Jefferson Davis Highway
Arlington, VA 22202
(703) 308-8097

Dec 23, 2002

RE: Aspergillus flavus AF36 ai#006456
Pending Section 3 Registration Number 71693-R, Petition 8E5001

Dear Shanaz:

Attached is an original signed copy of the classification of documents in the "Index of Documents Submitted along with the release letter. Please let me know if you have any questions.

Yours very truly,

Michael Braverman

Michael Braverman, Ph.D.
Biopesticide Coordinator
Interregional Research Project No. 4
Rutgers, The State University of New Jersey
The Technology Centre of New Jersey
681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390
(732) 932-9575 ext 610

CC: Peter Cotty(w/attachment)

Dr. Michael Braverman
Technology Center of New Jersey
Interregional Research Project No.4 (IR-4)
681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390

Dear Dr. Braverman:

***Aspergillus flavus* AF36 (ai# 006456)**
Pending Section 3 Registration EPA Reg. No. 71693-R
Pesticide Petition 8E5001

A docket has been established for the pending Federal Register documents regarding the application for the Section 3 registration and exemption from tolerance associated for use of *Aspergillus flavus* AF36 on cotton in Arizona and Texas. We are requesting classification from IR-4, Dr. Peter Cotty and all relevant parties regarding the documents listed on the attached indexes. The classification categories are described as follows.

A= Releasable to Anyone

B= Releasable to persons who submit a signed Affirmation of Non-multinational Status form. If "B documents appear on the index, a copy of the Affirmation is attached.

C= Claimed Confidential by the submitter. Requests for "C" documents will be processed under the Freedom of Information Act and EPA's public information regulations at 40 CFR Part 2, subpart B.

Please fill out the attached form, so that we can quickly finalize these pending Federal Register notices that are essential for the registration of your product. Your assistance is appreciated. If you have any further questions regarding this matter, do not hesitate to email me or call at 703-308-8097.

Sincerely,

Shanaz Bacchus, Chemist
Regulatory Action Leader
Biopesticides and Pollution Prevention Division

Enclosure

I, Michael Braverman, Biopesticide Coordinator
(insert name and title)

of Interregional Research Project No.4 (IR-4) have classified the following documents pertaining to the Active ingredient ***Aspergillus flavus* AF36** as indicated in the attached tables.

Signature/title/date Michael Braverman 12/20/02
Biopesticide Coordinator
IR-4 Project

Send completed form to:

ATTN: Shanaz Bacchus (7511C)
Biopesticides Pollution Prevention Division
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Index of Documents Submitted

(As of February 8, 2002)

OPP- (Docket #)
***Aspergillus flavus* AF36; Pending Section 3 Registration 71693-R; Establishment of Permanent tolerance exemption PP# 8E5001**

TITLE: (Title of document)	Author: (Last name, First name)	Document Date	Classification
1. **Bibliography** (attached)	EPA		
2. Application for Section 3 Registration for *Aspergillus flavus* AF36 for use on cotton in Arizona (AZ), Texas (TX). Form 8570-1	Antilla, Larry	8/8/02	B
3. Transmittal Letter and attachments	Braverman, Michael	8/12/02	B
4. Risk Assessment of *Aspergillus flavus* AF36 (Federal Register Notice of Filing)	EPA Federal Register Document	TBD	A
5. Petition for a permanent exemption from the requirement of a tolerance for residues of products containing the active ingredient *Aspergillus flavus* AF36 on cotton (PP8E5001)	Braverman, Michael	8/12/02	C
6. Specific References to Supporting Data for the pesticide petition from IR-4 for *Aspergillus flavus* AF36, and the pending Section 3 registration for (EPA File Symbol 71693-R; PP8E5001; OPP Identifier Number(s)). See references below.	See attached bibliography	See attached bibliography	C

Michael Braverman 12/20/02

TITLE: (Title of document)	Classification
43763400 USDA/ARS and IR-4 (1995) Submission of Product Chemistry, Toxicity, and Risk Data in Support of an Experimental Use Permit for Aspergillus flavus AF36. Transmittal of 5 Studies. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575	C
43763401 Cotty, P. (1995) Aspergillus flavus Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 85 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575	C
43763402 Cotty, P. (1995) Aspergillus flavus Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits, and Physical and Chemical Properties: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 8 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575	C
43763403 Cotty, P.; Hartman, C. (1995) Aspergillus flavus Isolate AF36--Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirements of a Tolerance for Aspergillus flavus for Use in Cotton Production: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 882 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575	C
43763404 Cotty, P. (1995) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents with Microbial Pest Control Agents: Statement of Finding No Hypersensitivity: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 4 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575	C
43763405 Cotty, P.; Hartman, C. (1995) Aspergillus flavus Isolate AF36: Product Performance Data: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 145 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575	C

Michael Braverman 12/20/02

TITLE: (Title of document)	Classification
43972400 Interregional Research Project No. 4 (1996) Submission of Product Analysis and Toxicology Data in Support of an Experimental Use Permit for Aspergillus flavus AF36. Transmittal of 3 Studies. SUBMITTED IN SUPPORT OF: 069224EX1	C
43972401 Cotty, P. (1996) Aspergillus flavus Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits: Amendment No. 1 to MRID No. 43763404: Lab Project Number: PR 52B: 52B. Unpublished study prepared by Southern Regional Research Center, USDA/ARS. 6 p. SUBMITTED IN SUPPORT OF: 069224EX1	C
43972402 Cotty, P. (1996) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents with Microbial Pest Control Agents: Statement of Finding of No Hypersensitivity: Amendment No. 1 to MRID No. 43763404: Lab Project Number: 52B: PR 52B. Unpublished study prepared by Southern Regional Research Center, USDA/ARS. 4 p. SUBMITTED IN SUPPORT OF: 069224EX1	C
43972403 Shelton, L. (1996) Acute Oral Toxicity Study in Rats: (Aspergillus flavus AF36): Final Report: Lab Project Number: M96AG84.6G31: MA M96AG84.6G31. Unpublished study prepared by Microbiological Associates, Inc. 59 p. SUBMITTED IN SUPPORT OF: 069224EX1	C
43990000 Interregional Research Project No. 4 (1996) Submission of Product Chemistry Data in Support of the Application for Experimental Use Permit for Apergillus flavus AF36. Transmittal of 1 Study. SUBMITTED IN SUPPORT OF: 069224EX1	C
43990001 Cotty, P. (1996) Aspergillus flavus Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process, and Discussion on the Formation of Unintentional Ingredients: Amendment No. 1 to MRID 43763401: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS, Southern Regional Research Center. 6 p. SUBMITTED IN SUPPORT OF: 069224EX1	C
44597000 Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerance of Aspergillus flavus isolate AF36 in/on Wheat. Transmittal of 1 Study. SUBMITTED IN SUPPORT OF: 8E5001	C

 Michael Braverman 12/20/02

TITLE: (Title of document)	Classification
44597001 Cotty, P.; Antilla, L. (1998) Aspergillus flavus Isolate AF36 Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 MRID 43763401: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, Arizona Cotton Research and Protection Council and Rutgers Univ. 38 p. SUBMITTED IN SUPPORT OF: 8E5001	C
44626100 Interregional Research Project No. 4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerance of Aspergillus flavus isolate AF36 in/on Cotton. Transmittal of 1 Study. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575	C
44626101 Cotty, P.; Antilla, L. (1998) Aspergillus flavus isolate AF36-Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits: Amendment No. 2 to MRID No. 43763402: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, and Arizona Cotton Research and Protection Council. 33 p. SUBMITTED IN SUPPORT OF: 069224EX1 SUBMITTED IN SUPPORT OF: 5E4575	C
44713700 Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerances of Aspergillus flavus in/on Cotton. Transmittal of 1 Study. SUBMITTED IN SUPPORT OF: 8E5001 SUBMITTED IN SUPPORT OF: 5E4575 SUBMITTED IN SUPPORT OF: 069224EX1	C
44713701 Cotty, P.; Antilla, L. (1998) Aspergillus Flavus isolate AF36--Amended Manufacturing Process--Amendment No.3: Lab Project Number: 52B. Unpublished study prepared by IR-4. 21 p. SUBMITTED IN SUPPORT OF: 8E5001 SUBMITTED IN SUPPORT OF: 5E4575 SUBMITTED IN SUPPORT OF: 069224EX1	C

Michael Braverman 12/20/02

TITLE: (Title of document)	Classification
45307200 USDA/ARS Southern Regional Research Center (2001) Submission of Environmental Fate Data in Support of the Petition for Tolerance of Aspergillus flavus Isolate AF36/Cotton in/on Cotton. Transmittal of 2 Studies. SUBMITTED IN SUPPORT OF: 5E4575 SUBMITTED IN SUPPORT OF: 069224EX1	C
45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus): Lab Project Number: 52B. Unpublished study prepared by Interregional Research Project No.4. 130 p. SUBMITTED IN SUPPORT OF: 5E4575 SUBMITTED IN SUPPORT OF: 069224EX1 Start here	C
45739100 Interregional Research Project No. 4 (2002) Submission of Toxicity and Exposure Data in Support of the Petition for Tolerance of Aspergillus flavus on Cotton. Transmittal of 4 Studies. SUBMITTED IN SUPPORT OF: 2E6497 45739103 Smith, D.; Cotty, P.; Braverman, M.; et al. (2002) Aspergillus flavus Isolate AF36: Non-Target Organism and Environmental Safety Information: Lab Project Number: IR-4 PR NO.52B: Unpublished study prepared by Soil & Crop Sciences, Southern Regional Research Center USDA/ARS, Rutgers University and Arizona Cotton Research and Protection Council. 57 p. SUBMITTED IN SUPPORT OF: 8E5001	C
45739101 Blanchard, E.; Carter, J. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Interim Report: Lab Project Number: UAR/006. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 86 p. {OPPTS 885.3150} SUBMITTED IN SUPPORT OF: 8E5001	C

Michael Braverman 12/20/02

Mike Braverman
<braverman@AESOP.RUTGERS.EDU>
05/09/02 01:39 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Peter Cotty <pjcotty@srrc.ars.usda.gov>, Phil Hutton/DC/USEPA/US@EPA
Subject: AF36 EUP Texas

Shanaz

Thank you for your time in discussing AF36. It was nice to finally meet you and have a chance to forward the toxicology studies.

To recap some of our discussion and information you requested.

As I relayed to you, the proposed EUP treatment for Texas is as follows:

County	Acres	Pounds
Calhoun	300	3,000
San Patrico	1,200	12,000
Nueces	500	5,000

You have the Calhoun, San Patricio and Nueces county maps showing the location of sites concerning the 400 foot buffer zones.

The EPA establishment number for the Arizona Facility as stated on the label is 71693-AZ-001. The spores are produced in Arizona and AF36 is originally from Arizona. A sample is certified in New Orleans.

I understand you are requesting the Annual Report and I have passed this message along to Peter.

I also understand you are requesting the patent number for AF36.

I have read the printed label with the modifications concerning the buffer, endangered species, washing statements etc. and it appears to have all the required components. Unfortunately I still could not make it come up or print correctly from my computer.

We will be developing an agenda for discussion of the AF36 registration process on May 30.

Your continued diligence on this matter is appreciated since the time for treatment is imminent

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

Mike Braverman
<braverman@AESOP.RUTGERS.EDU>

05/22/02 03:06 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Phil Hutton/DC/USEPA/US@EPA, Peter Cotty <pjcotty@srrc.ars.usda.gov>, Janet Andersen/DC/USEPA/US@EPA
Subject: RE: Meeting, May 30

Shanaz

As I understand, the guideline numbers 151-20 thru 151-25 are simply updated numbers OPPTS vs OECD . For example we have volumes covering 151A-1 and 151A-10 instead of 151-20, etc. These are already listed in the method of support. Please see page 5 of the EUP I submitted for one or several MRID numbers associated with those volumes which include Product Identity, Manufacturing Process, Unintentional Ingredients, Analysis of Samples, Certification of Ingredient Limits, etc. I will add the newer tox studies in the method of support list. I understand your desire to make good use of the meeting time so we need to be sure we are not covering old ground.

I would still appreciate a copy of the table you are referring to.

Is there still a chance for the EUP being approved in time for use in Texas?

Michael Braverman, Ph.D
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IR-4 Project, Rutgers University
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681 U.S. Highway 1 South
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Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

-----Original Message-----
From: Bacchus.Shanaz@epamail.epa.gov
[mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Tuesday, May 21, 2002 9:37 AM
To: Mike Braverman
Cc: Phil Hutton; Peter Cotty; Andersen.Janet@epamail.epa.gov
Subject: Re: Meeting, May 30

Mike:
Please include the items re: Data Required for Section 3 registration. You can find those in the letter I gave you and sent to Bill Biehn, Phil Wakelyn et al., on Dec. 14, 1999. It looks like you addresssed the mammalian, avian and honeybee studies required. We need to address gdlns 151-20 thru 151-25, analytical methods and contaminants (QA/QC]....look at the table attached at the end of the letter. Do let me know what reviews you have and need. Also, we need to know specifically what methods FDA uses for cotton, cottonseed oil and cotton byproducts. A printout of their methodology would be helpful.

In terms of the Data Matrix, please update the earlier submission, show what data address what guideline, etc. This is especially important now

that you have new studies to address some of the data requirements, and will help you to see whether the package is complete.

For the Section 3 registration, where (what states) do you wish to use AF36?

If you have any questions, do not hesitate to email me.
Thanks.
Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

Mike Braverman
<braverman@AESOP.RUTGERS.EDU>
05/20/02 03:03 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA, Phil Hutton/DC/USEPA/US@EPA
cc: Peter Cotty <pjcotty@srrc.ars.usda.gov>
Subject: Meeting, May 30

Dear Shanaz and Phil

Attached is the agenda for the AF36 meeting on May 30th. I have made some assumptions concerning EPA attendence. If some of the EPA names should be removed or others added please let me know.

Has the EUP for Texas been completed?

Thanks

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4
(See attached file: AGENDA FOR SECTION 3 REGISTRATION DISCUSSION.doc)

Mike Braverman
<braverman@AESOP.
RUTGERS.EDU>

D5/22/02 11:36 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Larry Antilla <LAntilla@AZcotton.com>, Phil Wakelyn <pwakelyn@cotton.org>, Janet Andersen/DC/USEPA/US@EPA, Peter Cotty <pjcotty@srrc.ars.usda.gov>, Phil Hutton/DC/USEPA/US@EPA
Subject: RE: Meeting, May 30

Dear Shanaz

Concerning your phone call request to change the date of the meeting from May 30 to May 29th, that is not possible since all plane/hotel reservations have already been set. We can change the starting time of the meeting from 1:30 to 1:00 PM on May 30. We had never previously set the meeting length as 1 hour and do not feel that is adequate to discuss all the issues.

I have the copy of the Dec 14, 1999 letter you gave me, but it does not have a table attached to it. Could you please fax it to me.

Could you also please arrange to have an overhead projector available for that room to facilitate discussion.

I will develop an updated list of Method of Support which will later be developed into a Data Matrix

We look forward to meeting at 1 PM on May 30

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

-----Original Message-----
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(mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Tuesday, May 21, 2002 9:37 AM
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Thanks.
Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

Mike Braverman
<braverman@AESOP.RUTGERS.EDU>

05/20/02 03:03 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA, Phil Hutton/DC/USEPA/US@EPA
cc: Peter Cotty <pjcotty@srrc.ars.usda.gov>
Subject: Meeting, May 30

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Thanks

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
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braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4
(See attached file: AGENDA FOR SECTION 3 REGISTRATION DISCUSSION.doc)

Mike Braverman
<braverman@AESOP.
RUTGERS.EDU>

05/20/02 03:03 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA, Phil Hutton/DC/USEPA/US@EPA
cc: Peter Cotty <pjcotty@srrc.ars.usda.gov>
Subject: Meeting, May 30

Dear Shanaz and Phil

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Thanks

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
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IR-4 Website www.cook.rutgers.edu/~ir4

AGENOA FOR SECTION 3 REGISTRATION DISCUSSION.doc

Mike Braverman
<braverman@AESOP.RUTGERS.EDU>

05/17/02 11:09 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Phil Hutton/DC/USEPA/US@EPA, Peter Cotty <pjcotty@srrc.ars.usda.gov>
Subject: RE: Counties/Patents

Shanaz

In response to your questions:

1) I assume this question relates back to this answer we provided in February:

AF36 is indeed endemic to Texas. Some data on this was previously submitted to EPA in association with the application for the Arizona registration. The chart of that data is herewith attached. This chart shows the percent of Aspergillus flavus communities composed of AF36. The communities presented are Aspergillus flavus on the cottonseed crops produced in 1991, 1992, and 1993 in both South and Central Texas. The number of mills sampled and the number of isolates examined are indicated. AF36 was detected in both South and Central Texas in every year examined.

We performed more recent surveys of the incidence of AF36 withing Aspergillus flavus communities resident on South Texas cottonseed crops in 1999 and 2000. In 1999 A. flavus was examined on 32 cottonseed samples from 11 gins (280 isolates examined). A. flavus AF36 was detected in all three areas examined (Coastal Bend, Upper Coast, and Winter Garden) at incidences of 1.67%, 5.00%, and 2.50%, respectively. These percentages represent the portion of the A. flavus community naturally composed of AF36. In 2000, A. flavus communities on 67 samples from 34 gins was examined (919 isolates examined). Aspergillus flavus AF36 was detected in the Coastal Bend Area at a 2.03% incidence, in the Rio Grande Valley Area at a 1.11% incidence, and in the Upper Coast Area at a 2.63% incidence. Only 39 isolates from the Winter Garden Area were examined in 2000 and no AF36 was detected among them.

The counties that will be treated (Nueces, San Patricio and Calhoun)are in South Texas. Regional descriptions can vary but I would characterize the three counties as the Coastal Bend. Calhoun County can also be considered Upper Coast. The following link is a map showing all the Texas counties. Since the organism is found throughout the state, such distinctions are only a geographical grouping and not pertinent to the EUP.

http://www.1uptravel.com/worldmaps/texas1.html

2) Here are links to the patents. Peter mentioned that the data used to support the patent were laboratory data.

The purpose of the EUP is to collect additional information. We hope to be able to do so in Texas.

http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1='5,294,442'.WKU.&OS=PN/5,294,442&RS=PN/5,294,442

http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1

&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1='5,171,686'.WKU.&OS=PN/5,171,686&RS=PN/5,171,686

Thanks

Michael Braverman, Ph.D
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Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/-ir4

-----Original Message-----
From: Bacchus.Shanaz@epamail.epa.gov
[mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Thursday, May 16, 2002 3:04 PM
To: Mike Braverman
Cc: Hutton.Phil@epamail.epa.gov; Peter Cotty
Subject: Counties/Patents

Mike:
1. I noticed that the incidence of AF36 in AZ ranged from 12% to 19%, whereas it is 2% AF36 in TX. Can you clarify the relationship between the areas tested (Texas South & Central, Coastal Bend, Upper Coast, Winter Garden and the Rio Grande Valley) and the areas proposed for treatment (i.e. do the Nueces, San Patricio and Calhoun counties fall into the areas where you have detected AF36?] I tried locating these counties on my Rand and McNally, but couldn't correlate the locations with the reports.

2. If you have electronic downloads of the patents, please send them to save me time searching the web.

Thanks.
Sincerely,
Shanaz Bacchus
703-308-8097

VCGTAB21.DOC

Mike Braverman
<braverman@AESOP.RUTGERS.EDU>

05/13/02 03:34 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Phil Hutton/DC/USEPA/US@EPA, Peter Cotty <pjcotty@srrc.ars.usda.gov>
Subject: RE: timing of applications/AZ

Shanaz

An estimate of the earliest possible date would be May 10 th in Arizona. Is this related to the wintering Plovers or some other issue?

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

-----Original Message-----
From: Bacchus.Shanaz@epamail.epa.gov
[mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Monday, May 13, 2002 1:49 PM
To: Mike Braverman
Cc: Phil Hutton; Peter Cotty
Subject: Re: timing of applications/AZ

Mike:
When is the earliest possible date that AF36 is applied in AZ?

Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C]
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

Mike Braverman
<braverman@AESOP.
RUTGERS.EDU>

05/13/02 08:50 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Peter Cotty <pjcotty@srrc.ars.usda.gov>, Phil Hutton/DC/USEPA/US@EPA
Subject: EUP reports and patent numbers

Dear Shanaz

Attached is the EUP report which is in 2 parts. The following is the information on the patent that you requested.

The two patents that apply to this product are: Use of Native Aspergillus flavus strains to prevent aflatoxin contamination, Assignee: The United States of America as represented by the U.S. Department of Agriculture, Washington, DC Patent Number 5,171,686 and Method for the control or prevention of aflatoxin contamination using a non-toxigenic strain of Aspergillus flavus, Assignee: The United States of America as represented by the U.S. Department of Agriculture, Washington, DC Patent Number 5,294,442.

If you need three hard copies of the EUP report through the front desk, please let me know and I can have them there by tomorrow morning.

Michael Braverman, Ph.D
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Appendix A EUP Report 2001.xls EUP report 2001.DOC

Mike Braverman
<braverman@AESOP.RUTGERS.EDU>

05/10/02 12:39 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Phil Hutton/DC/USEPA/US@EPA, Peter Cotty <pjcotty@srrc.ars.usda.gov>, pwakelyn@cotton.org, LAntilla@AZcotton.com, jnunley@stcga.org
Subject: RE: AF36 EUP Texas/label

Shanaz

Attached is the copy of the label from the floppy disk. As I mentioned it did not come out right on my screen and I assume its because I am formated for a different printer.

I don't quite understand why you are suggesting we remove the "In Texas" qualifier to the new edits of the label (Environmental Hazard section). Actually, now that I have looked into the plover I don't think any of the language is appropriate for the label. The alterations of requiring 3" vegetation around the field are not feasable for Arizona and affect the usefulness of the label. In addition this language has not been on the label previously and AF36 has been used in Arizona since 1996. After discussion with Peter Cotty, he feels that the "In Texas" qualifier should remain. Since the product is applied on wheat grains it will not be drifting like a spray potentially could into adjacent fields.

As you mentioned it depends on the time of application. The plover is an threatened/endangered species that migrates to Texas in the Winter, not May-June which is the application period in cotton so I question if it is relevant. It is also my understanding that the endangered species related language is due to the tox data not yet being reviewed. Considering the lack of toxicity we should not add language to the EUP that we will have to remove for the Section 3 label.

http://plover.fws.gov/FR_notice/FR_notice_summary.html?WAISdocID=973733278%2B1%2B2%2B0&WAISaction=retrieve

http://plover.fws.gov/FR_notice/index.html

We should have the annual report and the patent number you requested to you shortly.

Michael Braverman, Ph.D
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FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/-ir4

-----Original Message-----
From: Bacchus.Shanaz@epamail.epa.gov
[mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Thursday, May 09, 2002 3:10 PM
To: Mike Braverman

Cc: Phil Hutton; Peter Cotty
Subject: Re: AF36 EUP Texas/label

Thanks for your recap and for providing information rapidly. We have decided to remove the qualifier, "In Texas" from the label because some of the conditions may apply to AZ as well depending on the timing of the applications. Please email me the last copy of the label saved on the disk, so that we are dealing with the same label.
Thanks.
Shawn
Phone: 703-308-8097
Fax: 703-308-7026

LABelAF36EUPsb.wpd

Mike Braverman
<braverman@AESOP.RUTGERS.EDU>
05/09/02 01:39 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Peter Cotty <pjcotty@srrc.ars.usda.gov>, Phil Hutton/DC/USEPA/US@EPA
Subject: AF36 EUP Texas

Shanaz

Thank you for your time in discussing AF36. It was nice to finally meet you and have a chance to forward the toxicology studies.

To recap some of our discussion and information you requested.

As I relayed to you, the proposed EUP treatment for Texas is as follows:

County	Acres	Pounds
Calhoun	300	3,000
San Patrico	1,200	12,000
Nueces	500	5,000

You have the Calhoun, San Patricio and Nueces county maps showing the location of sites concerning the 400 foot buffer zones.

The EPA establishment number for the Arizona Facility as stated on the label is 71693-AZ-001. The spores are produced in Arizona and AF36 is originally from Arizona. A sample is certified in New Orleans.

I understand you are requesting the Annual Report and I have passed this message along to Peter.

I also understand you are requesting the patent number for AF36.

I have read the printed label with the modifications concerning the buffer, endangered species, washing statements etc. and it appears to have all the required components. Unfortunately I still could not make it come up or print correctly from my computer.

We will be developing an agenda for discussion of the AF36 registration process on May 30.

Your continued diligence on this matter is appreciated since the time for treatment is imminent

Michael Braverman, Ph.D
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Mike Braverman
<braverman@AESOP.RUTGERS.EDU>

05/01/02 09:39 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: jnunley@stcga.org, Phil Hutton/OC/USEPA/US@EPA, Peter Cotty <pjcotty@srrc.ars.usda.gov>, pwakelyn@cotton.org, Willie Nelson/DC/USEPA/US@EPA
Subject: RE: Meeting on May 7 on AF-36

Shanaz

I will arrive at BPPD around 9:30 AM on Monday May 6 and be there until the end of the day on Wednesday May 8. The primary purpose of my visit is to receive trainning as part of my sabbatical at EPA. I am open to meeting any time within that period. Since I will be meeting with several people, Willie Nelson is organizing my time schedule during my stay at BPPD. I know I am meeting with Andrew Brycelad on Tuesday also on a different matter, but I don't know the time. Please arrange the time with Willie Nelson.

I will be at Mike Watson's former desk on Billbug Blvd.

Thanks

Willie-Thanks again for all you hard work.

Michael Braverman, Ph.D
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-----Original Message-----
From: Bacchus.Shanaz@epamail.epa.gov
[mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Wednesday, May 01, 2002 9:30 AM
To: Mike Braverman
Cc: jnunley@stcga.org; Phil Hutton; Peter Cotty; pwakelyn@cotton.org; Willie Nelson
Subject: RE: Meeting on May 7 on AF-36

Mike:
What time will you be here next Tues, 5/7? Will 10 a.m be good for you to meet?

Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

Mike Braverman
<braverman@AESOP.RUTGERS.EDU>

04/30/02 01:35 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Willie Nelson/DC/USEPA/US@EPA, pwakelyn@cotton.org, Peter Cotty <pjcotty@srrc.ars.usda.gov>, Phil Hutton/DC/USEPA/US@EPA, jnunley@stcga.org
Subject: RE: Meeting on May 30 on AF-36

Shanaz

Hope everything is recovering for you with your medical situation.

For the EUP, since the Federal Register docket comment period for the Notice closed on April 24 I assume the Final Rule is about to come out?

As you are aware, the time for treatment for the Texas EUP is imminent and there is the time needed for approval from the Texas Department of Agriculture, shipment of materials , etc.

Most of all, for next week I just wanted to come by and say hello. For the Section 3, I would like your advice on anything that you foresee us needing for discussion during the meeting on May 30.

The most important thing for now is the EUP.
Your diligence is appreciated.

Michael Braverman, Ph.D
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IR-4 Project, Rutgers University
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Tel (732)932-9575 ext 610
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braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

-----Original Message-----
From: Bacchus.Shanaz@epamail.epa.gov
[mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Tuesday, April 30, 2002 11:23 AM
To: Mike Braverman
Cc: jnunley@stcga.org; Phil Hutton; Peter Cotty; pwakelyn@cotton.org; Willie Nelson
Subject: RE: Meeting on May 30 on AF-36

Last week, I was dealing with a medical emergency while working at home. Even though we missed each other, I was still dealing with AF36 and bombarding everyone with emails, sorting out the policy decisions with FR office, etc.

May 7 or 8 will be good. Please send me an email of the questions that you would like to discuss, just in case I need to research any of the issues.

Thanks,

Shanaz Bacchus, Chemist/RAL
703-308-8097 (phone)
703-308-7026 (fax)

Mike Braverman
<braverman@AESOP.RUTGERS.EDU>

04/30/02 10:45 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA, Phil Hutton/DC/USEPA/US@EPA
cc: Willie Nelson/DC/USEPA/US@EPA, pwakelyn@cotton.org, Peter Cotty <pjcotty@srrc.ars.usda.gov>, jnunley@stcga.org
Subject: RE: Meeting on May 30 on AF-36

Dear Shanaz and Phil

Since I will be at BPPD next week (May 6, 7, 8) I would be glad to discuss how we can assist in moving the process along for AF36. Shanaz- Sorry I missed you last week at BPPD.

Since Willie Nelson is coordinating my time at BPPD, please arrange things with him.

Michael Braverman, Ph.D
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Mike Braverman
<braverman@AESOP.RUTGERS.EDU>
04/15/02 12:58 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Gail Tomimatsu/DC/USEPA/US@EPA, Phil Hutton/DC/USEPA/US@EPA, Carl Etsitty/DC/USEPA/US@EPA, John Kough/DC/USEPA/US@EPA
Subject: RE: Texas counties/Endangered avians

Dear Shanaz

I look forward to the endangered species information. We want to utilize and interpret the information correctly so if there is a specific location that is of concern please let us know.

As we get closer to the actual time of study initiation we can get better information concerning study location . Along those lines, when we initially put the EUP together we requested nine counties. Although we requested those counties, we may not necessarily be locating plots in all of those 9 counties. The fields will most likely be in Calhoon, San Patricio and Nueces county which are in the maps you have.

Sorry for the confusion by including maps of Victoria and Refugio County. We will not be conducting trials in Victoria or Refugio County or any county other than the 9 originally requested.

We will get you more information as soon as possible.

Michael Braverman, Ph.D
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-----Original Message-----
From: Bacchus.Shanaz@epamail.epa.gov
[mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Thursday, April 11, 2002 4:51 PM
To: Mike Braverman
Cc: Tomimatsu.Gail@epamail.epa.gov; Hutton.Phil@epamail.epa.gov; Etsitty.Carl@epamail.epa.gov; Kough.John@epamail.epa.gov
Subject: Re: Texas counties/Endangered avians

Mike:
I received the summaries of the tox studies from Document Processing and am waiting for the maps. Your email attachment was 3 maps, while the Notice of Filing states that you would like to treat 9 counties. I have asked you to circle the areas to be treated. Please clarify on the maps where the following counties are and if Peter still intends to treat them: 9 counties in Texas including Nueces, San Patricio, Bee, Calhoon, Jackson, Wharton, Hildalgo, Cameron, and Willacy counties.

Gail Tomimatsu will send you some information on endangered avian

species in TX which may be helpful for you to consider for site selection during the EUP. It's important for you to consider the endangered avian species until we receive and review the avian and inhalation study.

I am copying the rest of the team, so that we can all be on the same page. If you have any questions, do not hesitate to email/call me.

Sincerely,

Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

Mike Braverman
<braverman@AESOP.
RUTGERS.EDU>

04/10/02 11:43 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: RE: FW: Map files

Shanaz

For the percent question it depends on what you mean by "all" Texas cotton fields.

On a statewide basis the projected cotton acreage in Texas is 5,700,000 acres so 2000 acres represents about 0.04%. On a regional basis cotton acreage in the Coastal Bend and Upper Coast areas will probably be between 650,000 and 750,000 acres, so 2000 acres is about 0.27 to 0.31% .

Since the locations have not been determined yet, there may be an opportunity to address any considerations in the site selection you may have.

In addition it is important that the fields selected contain a crop that is in good growth and typical commercial prodution practices are represented, therefore, a precise location will be determined just prior to application. I assume a group of potetential fields (Over 2,000 acres) can be designated as potential areas and the actual 2,000 acres to be treated would be selected form those potential areas.

I will not be here much longer today and will be out tomorrow.

Michael Braverman, Ph.D
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Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

-----Original Message-----
From: Bacchus.Shanaz@epamail.epa.gov
[mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Wednesday, April 10, 2002 9:51 AM
To: Mike Braverman
Cc: Hutton.Phil@epamail.epa.gov
Subject: RE: FW: Map files

Mike:
We did print out copies, but we would like to see the areas circled or annotated in some way to distinguish them from all cotton fields. So don't waste ink printing up other copies until you have all the information from Peter. We also need to know what percent of all cotton fields 2000 acres represent. I'll call to discuss later today.

Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

Mike Braverman
<braverman@AESOP.R
UTGERS.EDU>
04/09/02 02:11 PM

To: Phil Hutton/DC/USEPA/US@EPA
cc: Shanaz Bacchus/DC/USEPA/US@EPA
Subject: RE: FW: Map files

Phil and Shanaz

In talking to Peter we really don't know right now. The plots will be in fields within these counties. The final determinations will be made at the end of the month.

Are there particular areas you are concerned about? Also , our petition states that there will be a 400 ft buffer zone in regard to healthcare and school facilities.

Concerning copies, I guess I slipped up and I only sent one to each of you but I think you have a printout or two that you made off of the e-mail which makes 3-4 total. If you still need more hardcopies, I can print more and send them.

Thanks.

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
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Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

-----Original Message-----
From: Hutton.Phil@epamail.epa.gov [mailto:Hutton.Phil@epamail.epa.gov]

Sent: Tuesday, April 09, 2002 10:35 AM
To: Mike Braverman
Cc: Shanaz Bacchus
Subject: Re: FW: Map files

Mike:

The maps show the schools and hospitals, but don't show the areas where applications will be made. These are necessary to the evaluation of the EUP amendment.

Phil

Mike Braverman
<braverman@AESOP.
RUTGERS.EDU>

To: Phil Hutton/DC/USEPA/US@EPA
cc: Shanaz Bacchus/DC/USEPA/US@EPA
Subject: RE: FW: Map files

04/09/02 02:11 PM

Phil and Shanaz

In talking to Peter we really don't know right now. The plots will be in fields within these counties. The final determinations will be made at the end of the month.

Are there particular areas you are concerned about? Also , our petition states that there will be a 400 ft buffer zone in regard to healthcare and school facilities.

Concerning copies, I guess I slipped up and I only sent one to each of you but I think you have a printout or two that you made off of the e-mail which makes 3-4 total. If you still need more hardcopies, I can print more and send them.

Thanks.

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
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FAX (732)932-8481
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IR-4 Website www.cook.rutgers.edu/~ir4

-----Original Message-----
From: Hutton.Phil@epamail.epa.gov [mailto:Hutton.Phil@epamail.epa.gov]
Sent: Tuesday, April 09, 2002 10:35 AM
To: Mike Braverman
Cc: Shanaz Bacchus
Subject: Re: FW: Map files

Mike:

The maps show the schools and hospitals, but don't show the areas where applications will be made. These are necessary to the evaluation of the EUP amendment.

Phil

Mike Braverman
<braverman@AESOP.
RUTGERS.EDU>

04/08/02 11:48 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: FW: FedEx shipment 791183905000

Shanaz

Now FEDEX says your copy should be there too.

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

-----Original Message-----
From: sysdeliv@esprim5.prod.fedex.com
[mailto:sysdeliv@esprim5.prod.fedex.com]
Sent: Monday, April 08, 2002 11:21 AM
To: braverman@AESOP.RUTGERS.EDU
Subject: FedEx shipment 791183905000

Our records indicate that the shipment sent from Michael Braverman/IR-4 PROJECT/RUTGERS U
to Shanaz Bacchus/US EPA has been delivered.
The package was delivered on 04/8/2002 at 11:10 AM and signed for or released by B.USEN.

The ship date of the shipment was 04/5/2002.

The tracking number of this shipment was 791183905000.

Thank you for shipping with FedEx Ship Manager at FedEx.com.
https://www.fedex.com/cgi-bin/ship_it/interNetShip/

To track the status of this shipment on line click on the following:
http://www.fedex.com/cgi-bin/tracking?tracknumbers=791183905000&action=track&language=english&cntry_code=us

Disclaimer

FedEx has not validated the authenticity of any email address.

Mike Braverman
<braverman@AESOP.
RUTGERS.EDU>

04/08/D2 11:17 AM

To: Phil Hutton/DC/USEPA/US@EPA
cc: Shanaz Bacchus/DC/USEPA/US@EPA
Subject: FW: FedEx shipment 792012685889

Phil

Glad to hear the printing turned out DK.

According to FEDEX, the hard copy should already be there and signed for by B. USEN. I sent one to both Shanaz and you on Friday , but apparently yours came through first.

Thanks

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/-ir4

-----Original Message-----
From: sysdeliv@esprim5.prod.fedex.com
[mailto:sysdeliv@esprim5.prod.fedex.com]
Sent: Monday, April 08, 2002 11:18 AM
To: braverman@AESOP.RUTGERS.EDU
Subject: FedEx shipment 792012685889

Our records indicate that the shipment sent from Michael Braverman/IR-4 PROJECT/RUTGERS U
to Phil Hutton/US EPA has been delivered.
The package was delivered on 04/8/2002 at 11:10 AM and signed for or released by B.USEN.

The ship date of the shipment was 04/5/2002.

The tracking number of this shipment was 792012685889.

Thank you for shipping with FedEx Ship Manager at FedEx.com.
https://www.fedex.com/cgi-bin/ship_it/interNetShip/

To track the status of this shipment on line click on the following:
http://www.fedex.com/cgi-bin/tracking?tracknumbers=792012685889&action=track&language=english&cntry_code=us

Disclaimer

FedEx has not validated the authenticity of any email address.

Mike Braverman
<braverman@AESOP.
RUTGERS.EDU>

04/05/02 01:45 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Phil Hutton/DC/USEPA/US@EPA
Subject: FW: Map files

Dear Shanaz

I am following up on your request for maps showing schools, etc. in Texas for the Aspergillus flavus EUP. Just received these maps from Peter.

I don't know if you have Power Point and a color printer but I thought it wouldn't hurt to send an electronic copy first. Of course I will be sending these to you by FEDEX also.

Have a nice weekend.

Michael Braverman, Ph.D
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FAX (732)932-8481
braverman@aesop.rutgers.edu
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-----Original Message-----
From: Peter Cotty [mailto:pjcotty@srrc.ars.usda.gov]
Sent: Friday, April 05, 2002 11:47 AM
To: braverman@AESOP.RUTGERS.EDU
Subject: Map files

sanpat-nueces-refugio1.ppt victoria-calhoun.ppt AF36mapletter.wpd

Mike Braverman
<braverman@AESOP.
RUTGERS.EDU>

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: EUP, Section 3 Registration AF36

04/03/02 10:31 AM

Shanaz

Concerning your question about the state registration process subsequent to EPA approval of AF36, Peter Cotty will be handling the registrations for AZ and TX for the EUP. The Arizona Cotton Council will be handling registrations in all states when the Section 3 is approved.

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
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North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

Mike Braverman
<braverman@AESOP.RUTGERS.EDU>

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: RE:

03/29/02 08:23 AM

Shanaz

By waterways I assume you mean natural bodies of water such as rivers, lakes, streams, ocean and not irrigation and drainage ditches. Can you define what you mean by waterway.

Thanks

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
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IR-4 Website www.cook.rutgers.edu/~ir4

-----Original Message-----
From: Bacchus.Shanaz@epamail.epa.gov
[mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Thursday, March 28, 2002 4:15 PM
To: Mike Braverman
Subject: Re:

Thanks for your note re summaries of tox data by FedEx shipment 791802505482. I will check to make sure it is here. In the meanwhile, will you please ask Peter to include proximity to waterways when he gets the maps for the proposed EUP for Texas (TX)? I noticed that all the studies related to aquatic organisms were waived for the Arizona (AZ) EUP. The maps generated for AZ, also showed proximity to schools, daycare and nursing home facilities. We need the same information for TX.

Thanks,

Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

Mike Braverman
<braverman@AESOP.RUTGERS.EDU>
03/28/02 12:28 PM

To: Phil Hutton/DC/USEPA/US@EPA, Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: FW: FedEx shipment 791802505482

Dear Shanaz and Phil

FEDEX indicates that the mail has been received and signed for by D. ALLEN. This is the information I e-mailed to you concerning the toxicology summary.

I am working at home today.

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

-----Original Message-----
From: sysdeliv@esprim5.prod.fedex.com
[mailto:sysdeliv@esprim5.prod.fedex.com]
Sent: Thursday, March 28, 2002 12:11 PM
To: braverman@AESOP.RUTGERS.EDU
Subject: FedEx shipment 791802505482

Our records indicate that the shipment sent from Michael Braverman/IR-4 PROJECT/RUTGERS U
to Shanaz Bacchus/US EPA has been delivered.
The package was delivered on 03/28/2002 at 11:11 AM and signed for or released by D.ALLEN.

The ship date of the shipment was 03/26/2002.

The tracking number of this shipment was 791802505482.

Thank you for shipping with FedEx Ship Manager at FedEx.com.
https://www.fedex.com/cgi-bin/ship_it/interNetShip/

To track the status of this shipment on line click on the following:
http://www.fedex.com/cgi-bin/tracking?tracknumbers=791802505482&action=track&language=english&cntry_code=us

Disclaimer

FedEx has not validated the authenticity of any email address.

Our records indicate that the shipment sent from Michael Braverman/IR-4 PROJECT/RUTGERS U
to Phil Hutton/US EPA has been delivered.
The package was delivered on 03/28/2002 at 11:11 AM and signed for

or released by D.ALLEN.

The ship date of the shipment was 03/26/2002.

The tracking number of this shipment was 792714374083.

Thank you for shipping with FedEx Ship Manager at FedEx.com.
https://www.fedex.com/cgi-bin/ship_it/interNetShip/

To track the status of this shipment on line click on the following:
http://www.fedex.com/cgi-bin/tracking?tracknumbers=792714374083&action=track
&language=english&cntry_code=us

Disclaimer

FedEx has not validated the authenticity of any email address.

Mike Braverman
<braverman@AESOP.
RUTGERS.EDU>

03/23/02 03:38 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: RE: Summary

Shanaz

Should that go through the document processing desk? If not, what address should I use?

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

-----Original Message-----
From: Bacchus.Shanaz@epamail.epa.gov
(mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Thursday, March 21, 2002 9:25 AM
To: Mike Braverman
Subject: Re: Summary

Phil expects that you submit it by FEDEX, not email...ok?

Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

Mike Braverman
<braverman@AESOP.
RUTGERS.EDU>

03/21/02 10:03 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: RE: Summary/addendum

OK

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/-ir4

-----Original Message-----
From: Bacchus.Shanaz@epamail.epa.gov
[mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Thursday, March 21, 2002 9:27 AM
To: Mike Braverman
Subject: Re: Summary/addendum

I will accept email as a heads-up, followed by official signed transmittal letter and FEDEX.

Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

Mike Braverman
<braverman@AESOP.RUTGERS.EDU>

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: Summary

03/21/02 08:53 AM

Shanaz

I have prepared and forwarded a summary of the toxicology work to Peter Cotty for his comment. I know he is on the road in TX and does not check his e-mail on the road. I have copied a cooperator in TX and hope Peter will get it through him.

Thanks for your patience

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

Mike Braverman
<braverman@AESOP.RUTGERS.EDU>

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc:
Subject: RE: AF36 progress

03/19/02 07:04 PM

Shanaz

I have pasted Peter's responses which follow the numbered questions from our last discussion below. I would have to consult with him about potential submission dates for the avian and mammalian study. I have the Bee study, and beleive the avian is complete, but is awaiting the completed reports. The mammalian is still being done so I don't wan't to speculate on that. I could send the bee study in a few weeks. I would guess the avian study could be submitted in a month or so but Peter would be a better judge of that. In addition, I have other packages that I am working on.

Hope these answers of Peter's help.

The following are my responses to the inquiry from EPA.

1. Are the cultural or environmental conditions in AZ and TX similar enough so
that you are sure that infection will occur at the same time.

The time of infection differs among fields and between years in Arizona and we expect this to be the same in Texas. The industry has given us an extensive database concerning the incidences of toxin in the cottonseed crop in South Texas and there are several aspects that are similar to what we see in Arizona. The important element for success of our strategy is that the A. flavus community declines during the winter months and increases rapidly during the warm months This is similar to what we see in Arizona.

2. Are the soil conditions similar enough between AZ and TX such that there is
similar prevelance of aflatoxin producing organisms in TX.

The soils vary considerably throughout Arizona and South Texas. However, areas with high aflatoxin contamination in the two areas have in common a high prevalence of the high aflatoxin producing S strain of A. flavus. This surprised us because the S strain was initially described from Arizona. However, in portions of South Texas the S strain is just as common as in the areas of Arizona with the highest incidences of S strain. A major goal of treatments is to displace the highly toxigenic S strain isolates.

3. In Texas, what is the proximity of cotton to other crops that would be treated with AF36 and is there any risk-host range associated with the application. I pointed out there are other crops that would benefit such as corn.

The primary crop rotation in the treatment areas is cotton-corn-sorghum. All these crops have been grown in the treatment areas of Arizona over the past three years. There are high quantities of A. flavus throughout the environment in agricultural fields of South Texas. The A. flavus strain proposed for use is native throughout the area. Thus the crops are continually exposed to A. flavus already.

4. Repeated the requests for TX county maps.

We are working with the South Texas Boll Weevil Eradication Foundation to develop the requested maps. We anticipate that these should be completed prior to treatment. I have forwarded your concern to the involved parties.

5. Are any endangered species present in the TX counties.

I am certain there must be some endangered species. We do not have details on this aspect. However, the same rational as that used in Arizona applies. A. flavus occures at high levels throughout the area and thus species are already exposed to significant levels of A. flavus. Aflatoxin producers are common on crops and in soils throughout the area. Displacement of the aflatoxin producers with a strain that does not produce aflatoxins should provide a benefit to endangered species. The atoxigenic strain already is common throughout the proposed treatment area. Toxicity studies in insects, mammals, and birds suggest there is no pathogenicity or toxicity concern.

6. Can you differentiate between L and S strains in the soil as per letter of Dec 14 , 1999.

Yes. This is done routinely as it has been done during the Experimental Program in Arizona.

7. What's the status of the tox work that is going on.

We have completed the Bee, Avian pulmonary and Mammalian pulmonary studies requested by EPA. The results suggest there are no pathogenicity or toxicity problems with Aspergillus flavus AF36. We are waiting for the formal reports from the toxicology laboratory. We anticipate meeting with EPA in the next few months to review the results and discuss the section 3 registration for Arizona.

I hope these responses are sufficient. I leave for Texas around 3 PM and will meet with some of our industry partners over the next week as we take soil samples throughout the South Texas production areas.

We all greatly appreciate the continued assistance of yourself and IR-4.

Sincerely,

--Peter.

Peter J. Cotty, Ph.D.
Research Plant Pathologist
Southern Regional Research Center
Agricultural Research Service
United States Department of Agriculture
1100 Robert E. Lee Blvd.
New Orleans, LA 70124

pjcotty@srrc.ars.usda.gov
Phone: 504-286-4391
FAX: 504-286-4496

Michael Braverman, Ph.D

Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4ut

-----Original Message-----
From: Bacchus.Shanaz@epamail.epa.gov
[mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Tuesday, March 19, 2002 2:50 PM
To: Mike Braverman
Subject: Re: AF36 progress

I trust that this week is a bit more settled than last week.

1. Please send me an email describing the progress made on the research for AF36 (mammalian and avian studies) and give me an idea of an approximate time for the data submission...just ball park time will do. We're having a team meeting tomorrow, after which I will let you know what other issues need to be addressed for the use in TX.
2. Did you find the Dec 14, 1999 letter outlining data requirements? What progress have IR-4/ARS made towards developing another tool/method to differentiate AF36 from other A. flavus species? I may have to answer this question when we brief upper management.

Thanks,

Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

152-37
43972402 Cotty, P. (1996) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents with Microbial Pest Control Agents: Statement of Finding of No Hypersensitivity: Amendment No. 1 to MRID No. 43763404: Lab Project Number: 52B: PR 52B. Unpublished study prepared by Southern Regional Research Center, USDA/ARS. 4 p.

SUBMITTED IN SUPPORT OF: 069224EX1

152-37
43763404 Cotty, P. (1995) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents with Microbial Pest Control Agents: Statement of Finding No Hypersensitivity: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 4 p.

152-15 Hypersensitivity

SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

152-37
45739104 Antilla, L.; Cotty, P.; Braverman, M. (2002) Aspergillus flavus Isolate AF336: Hypersensitivity Incidents: Lab Project Number: 52B. Unpublished study prepared by Arizona Cotton Research and Protection Council, Southern Regional Research Center and Rutgers University. 18 p.

SUBMITTED IN SUPPORT OF: 2E6497

154-24
45739102 Mayer, D. (2001) Honey Bee Field Study of Aspergillus flavus AF36 in Cotton: Lab Project Number: WSU 00-011. Unpublished study prepared by Washington State University. 30 p. {OPPTS 850.3040, 885.4380}

SUBMITTED IN SUPPORT OF: 2E6497

SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

151-25
151-20
151-26
43763402 Cotty, P. (1995) Aspergillus flavus Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits, and Physical and Chemical Properties: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 8 p.

SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

151-21
43972401 Cotty, P. (1996) Aspergillus flavus Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits: Amendment No. 1 to MRID No. 43763404: Lab Project Number: PR 52B: 52B. Unpublished study prepared by Southern Regional Research Center, USDA/ARS. 6 p.

SUBMITTED IN SUPPORT OF: 069224EX1

152-30
43972403 Shelton, L. (1996) Acute Oral Toxicity Study in Rats: (Aspergillus flavus AF36): Final Report: Lab Project Number: M96AG84.6G31: MA M96AG84.6G31. Unpublished study prepared by Microbiological Associates, Inc. 59 p.

SUBMITTED IN SUPPORT OF: 069224EX1

152-32
45739101 Blanchard, E.; Carter, J. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Interim Report: Lab Project Number: UAR/006. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 86 p. {OPPTS 885.3150}

SUBMITTED IN SUPPORT OF: 2E6497

21
151-~~11~~
44713701 Cotty, P.; Antilla, L. (1998) Aspergillus Flavus isolate AF36--Amended Manufacturing Process--Amendment No.3: Lab Project Number: 52B. Unpublished study prepared by IR-4. 21 p.

SUBMITTED IN SUPPORT OF: 8E5001
SUBMITTED IN SUPPORT OF: 5E4575
SUBMITTED IN SUPPORT OF: 069224EX1

151-20
43990001 Cotty, P. (1996) Aspergillus flavus Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process, and Discussion on the Formation of Unintentional Ingredients: Amendment No. 1 to MRID 43763401: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS, Southern Regional Research Center. 6 p.

151-21

SUBMITTED IN SUPPORT OF: 069224EX1

151-20
151-21
151-22
151-25
44597001 Cotty, P.; Antilla, L. (1998) Aspergillus flavus Isolate AF36 Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 MRID 43763401: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, Arizona Cotton Research and Protection Council and Rutgers Univ. 38 p.

SUBMITTED IN SUPPORT OF: 8E5001

151-20
151-21
151-22
43763401 Cotty, P. (1995) Aspergillus flavus Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 85 p.

156A-2

43763405 Cotty, P.; Hartman, C. (1995) Aspergillus flavus Isolate AF36: Product Performance Data: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 145 p.

SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

45739100 Interregional Research Project No. 4 (2002) Submission of Toxicity and Exposure Data in Support of the Petition for Tolerance of Aspergillus flavus on Cotton. Transmittal of 4 Studies.

SUBMITTED IN SUPPORT OF: 2E6497

45739103 Smith, D.; Cotty, P.; Braverman, M.; et al. (2002) Aspergillus flavus Isolate AF36: Non-Target Organism and Environmental Safety Information: Lab Project Number: IR-4 PR NO.52B: Unpublished study prepared by Soil & Crop Sciences, Southern Regional Research Center USDA/ARS, Rutgers University and Arizona Cotton Research and Protection Counsil. 57 p.

SUBMITTED IN SUPPORT OF: 2E6497

43763400 USDA/ARS and IR-4 (1995) Submission of Product Chemistry, Toxicity, and Risk Data in Support of an Experimental Use Permit for Aspergillus flavus AF36. Transmittal of 5 Studies.

SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

151-12 43763401 Clinical. Infect.

151-15
151-10
151-13

44626101 Cotty, P.; Antilla, L. (1998) Aspergillus flavus isolate AF36-Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits: Amendment No. 2 to MRID No. 43763402: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, and Arizona Cotton Research and Protection Council. 33 p.

SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

45307200 USDA/ARS Southern Regional Research Center (2001) Submission of Environmental Fate Data in Support of the Petition for Tolerance of Aspergillus flavus Isolate AF36/Cotton in/on Cotton. Transmittal of 2 Studies.

SUBMITTED IN SUPPORT OF: 5E4575
SUBMITTED IN SUPPORT OF: 069224EX1

for 71GB R these are submitted for an oral

45307202 Cotty, P. (2001) Aspergillus flavus Isolate AF36 Non-target Organism and Environmental Safety Information (Soil and Air Monitoring of Populations of A. flavus): Lab Project Number: 52B. Unpublished study prepared by Interregional Research Project No.4. 130 p.

SUBMITTED IN SUPPORT OF: 5E4575
SUBMITTED IN SUPPORT OF: 069224EX1

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus): Lab Project Number: 52B. Unpublished study prepared by Interregional Research Project No.4. 130 p.

SUBMITTED IN SUPPORT OF: 5E4575
SUBMITTED IN SUPPORT OF: 069224EX1

-12 + acute inhal
-13 Primary ~~dermal~~ eye irrt
-14 Prim. dermal irrt

43763403 Cotty, P.; Hartman, C. (1995) Aspergillus flavus Isolate AF36--Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirements of a Tolerance for Aspergillus flavus for Use in Cotton Production: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 882 p.

SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

PC Code 006456 - - Sorted by Guideline

GDLN

43972400 Interregional Research Project No. 4 (1996) Submission of Product Analysis and Toxicology Data in Support of an Experimental Use Permit for Aspergillus flavus AF36. Transmittal of 3 Studies.

SUBMITTED IN SUPPORT OF: 069224EX1

43990000 Interregional Research Project No. 4 (1996) Submission of Product Chemistry Data in Support of the Application for Experimental Use Permit for Apergillus flavus AF36. Transmittal of 1 Study.

SUBMITTED IN SUPPORT OF: 069224EX1

44597000 Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerance of Aspergillus flavus isolate AF36 in/on Wheat. Transmittal of 1 Study.

SUBMITTED IN SUPPORT OF: 8E5001

44626100 Interregional Research Project No. 4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerance of Aspergillus flavus isolate AF36 in/on Cotton. Transmittal of 1 Study.

SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

44713700 Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerances of Aspergillus flavus in/on Cotton. Transmittal of 1 Study.

SUBMITTED IN SUPPORT OF: 8E5001
SUBMITTED IN SUPPORT OF: 5E4575
SUBMITTED IN SUPPORT OF: 069224EX1

Merge 8E 5001
5E 4575
2E6497

These also belong to 006456

69224-EUP-1 should have
all 006456 <u>except</u> those in 2E6497

John Jamula
10/24/02 09:16 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Teresa Downs/DC/USEPA/US@EPA
Subject: Re: Aspergillus flavus AF36

Shanaz,

I searched for those two numbers specifically..... and found nothing... JJ.
Shanaz Bacchus

Shanaz Bacchus
10/24/02 09:13 AM

To: John Jamula/DC/USEPA/US@EPA
cc: Teresa Downs/DC/USEPA/US@EPA
Subject: Re: Aspergillus flavus AF36

John:
Thanks for the bib on ai# 006456. The 2 numbers below did not show up. Can you do a run (by gdln) on these 2 numbers and send me an electronic copy?

71693-R
PP# 2E6511

Looking forward to hearing from you,
shawn

Phone: 703-308-8097
Fax: 703-308-7D26
John Jamula

John Jamula
10/23/02 04:03 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Teresa Downs/DC/USEPA/US@EPA
Subject: Re: Aspergillus flavus AF36

Shanaz,

I hope that this helps.....

c006456x.wpd
Shanaz Bacchus

Shanaz Bacchus
10/23/02 03:43 PM

To: John Jamula/DC/USEPA/US@EPA, Teresa Downs/DC/USEPA/US@EPA
cc:
Subject: Aspergillus flavus AF36

A. flavus AF36 was a new active ingredient in an EUP for the last 6 years during which time the applicant was generating efficacy data to support the claim for aflatoxin control in cotton. I am trying to sort out their data submissions which have been piece meal. Because of this, they may have been given more than 1 petition #, and data for the registration may have been submitted for the petition, whereas it should have been linked to the registration #. The applicant is new at the process and somewhat confused.

To help me sort out the confusions, can you do an electronic bibliography, by guideline, for me on the following:

1. active ingredient # 006456
2. 69224- EUP-1
3. 71693-R
4. **PP#** 2E6497
5. **PP# 5E4575**
6. **PP#** 2E6511

I figure that the search by ai # will show me if there is another petition # associated with the submissions....is that a correct assumption?
If you have any questions, do not hesitate to call/email me.
Thanks for your help.
Sincerely

Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

BPPD PRAT ACTION CODING FORM

PM 30: Janet Andersen

REVIEWER: Baccitus
(ASSIGNED BY: PDK)

EPA REG./FILE SYMBOL 71693-R

ACTION CODE B1

SUBMISSION BARCODE

Date on Application 12-10-98

EPA Received Date 12-15-98

PM Received Date 12-16-98

Response to numbered items

Assigned in PRAT YES ____ NO ✓ No PC Code

Completed by: S. Diana Hudson Date 12-29-98

FINAL ACTION

Response Code ____

Response Date: / /

MOS: ____ (1) ~~Cite All~~

____ (4) ~~Not Applicable~~

____ (8) ~~Selective~~

CRP: Yes ____ No ____

Restricted Use: Yes ____ No ✓

Manufacturing Use: Yes ____ No ____

Exclusive Use: Yes ____ No ____

John Jamula
10/24/02 09:16 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Teresa Downs/DC/USEPA/US@EPA
Subject: Re: Aspergillus flavus AF36

Shanaz,

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Shanaz Bacchus

Shanaz Bacchus
10/24/02 09:13 AM

To: John Jamula/DC/USEPA/US@EPA
cc: Teresa Downs/DC/USEPA/US@EPA
Subject: Re: Aspergillus flavus AF36

John:
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71693-R
PP# 2E6511

Looking forward to hearing from you,
shawn

Phone: 703-308-8097
Fax: 703-308-7026
John Jamula

John Jamula
10/23/02 04:03 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Teresa Downs/DC/USEPA/US@EPA
Subject: Re: Aspergillus flavus AF36

Shanaz,

I hope that this helps.....

c006456x.wpd
Shanaz Bacchus

Shanaz Bacchus
10/23/02 03:43 PM

To: John Jamula/DC/USEPA/US@EPA, Teresa Downs/DC/USEPA/US@EPA
cc:
Subject: Aspergillus flavus AF36

A. flavus AF36 was a new active ingredient in an EUP for the last 6 years during which time the applicant was generating efficacy data to support the claim for aflatoxin control in cotton. I am trying to sort out their data submissions which have been piece meal. Because of this, they may have been given more than 1 petition #, and data for the registration may have been submitted for the petition, whereas it should have been linked to the registration #. The applicant is new at the process and somewhat confused.

To help me sort out the confusions, can you do an electronic bibliography, by guideline, for me on the following:

1. active ingredient # 006456
2. 69224-EUP-I
3. 71693-R
4. **PP#** 2E6497
5. **PP# 5E4575**
6. **PP#** 2E6511

I figure that the search by ai # will show me if there is another petition # associated with the submissions....is that a correct assumption?
If you have any questions, do not hesitate to call/email me.
Thanks for your help.
Sincerely

Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

p. Hutton

BPPD PRAT ACTION CODING FORM

FM 90: Janet Andersen

REGISTRANT/COMPANY NAME: Arizona Cotton Research Protection

Fast Track: Yes☐ No☐
Reviewer BACCHUS
Assigned by POH

EPA REG./FILE SYMBOL 71693-R

[Note: If Fast Track, you may need to change Reviewer's Name in PRAT.]

ACTION CODE 731

(New A.I/EUP'S/Tolerances: Yes☐ No☐)

DATE OF APPLICATION 8/8/02

EPA RECEIVED DATE 8/14/02

BPPD RECEIVED DATE 8/22/02

SUBMISSION BARCODE 5620798

package incomplete need DW requests

ASSIGNED IN PRAT: Yes☒ No☐

COMPLETED BY T. Bethune DATE 8/27/02

LOGGED IN BRATS: Yes☑ No☐ DATE 8-29-02 COMPLETED BY NQ

RAL RECEIVED _____ DATE _____
(RAL initials)

FINAL ACTION

RESPONSE CODE: _____

RESPONSE DATE: _____

MOS: _____ (1) Cite All
_____ (4) Not Applicable
_____ (8) Selective

CRP	Yes☐	No☐
Restricted Use:	Yes☐	No☐
Manufacturing Use:	Yes☐	No☐
Exclusive Use:	Yes☐	No☐

NET Copy to Maureen Sherrill (DA) 8-14-2

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95 B

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number: 279717

Application for Pesticide - Section I

1. Company/Product Number: 71693 — R

2. EPA Product Manager: S. BACCHUS

PM#

3. Proposed Classification: [X] None [ ] Restricted

4. Company/Product (Name): ASPERGILLUS FLAVUS AF36

5. Name and Address of Applicant (Include ZIP Code):
Arizona Cotton Research & Protection Council
3721 E. Wier Avenue
Phoenix, Arizona 85040-2933

[X] Check if this is a new address

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Superceds previous submission dated June 26, 1998
Data (MRID) numbers from previous section 3 submission and Experimental Use Permit submission are cited.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging: [ ] Yes [X] No
* Certification must be submitted

Unit Packaging: [ ] Yes [X] No
If "Yes" Unit Packaging wgt. ____ No. per container ____

Water Soluble Packaging: [ ] Yes [X] No
If "Yes" Package wgt ____ No. per container ____

2. Type of Container: [ ] Metal [X] Plastic Bag [ ] Glass [ ] Paper [X] Other (Specify) Bulk Bags, Bulk Boxes

3. Location of Net Contents Information: [ ] Label [ ] Container

4. Size(s) Retail Container: Plastic Bag: 50 lbs. Bulk Bag/Box: 1000-3000 lbs

5. Location of Label Directions: [X] On Label

6. Manner in Which Label is Affixed to Product: [X] Lithograph Paper glued Stenciled [ ] Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name: LARRY ANTILLA
Title: STAFF DIRECTOR
Telephone No. (Include Area Code): (602) 438-0059

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature: [signature]
3. Title: STAFF DIRECTOR
4. Typed Name: LARRY ANTILLA
5. Date: 8-8-02

6. Date Application Received (Stamped)

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
279717

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification ☐ None ☐ Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant *(Include ZIP Code)* ☐ *Check if this is a new address*	6. **Expedited Review.** (In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

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6. Date Application Received (Stamped)

2. Signature	3. Title
4. Typed Name	5. Date

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

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EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
279717

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification ☐ None ☐ Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant *(Include ZIP Code)* ☐ *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

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☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

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Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

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☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

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1-5. Self-explanatory.
6. EPA Use Only.

ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
3721 East Wier Avenue
Phoenix, Arizona 85040-2933
(602) 438-0059 - Phone
(602) 438-0407 - Fax

August 8, 2002

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266 A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Subject: Aspergillus flavus AF-36 Arizona Cotton Research and Protection Council Company Number 71693

Dear Dr. Andersen:

Enclosed please find our application for Pesticide Registration for the above subject product. Enclosed also are: Proposed label (5 copies); confidential statement of formula; certification with respect to citation of data statement, etc.

In support of this application, please refer to the petition entitled "Aspergillus flavus AF-36 Tolerance Exemption in or on Cotton".

This petition was submitted by IR-4.

As per PR Notice 88-4, the registration of the above use is exempt from fees.

Sincerely,

Larry Antilla
Director

Registration Volume

Aspergillus flavus AF-36

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APPLICATION FOR PESTICIDE REGISTRATION ..... Reference 2

CONFIDENTIAL STATEMENT OF FORMULA ..... Reference 3

PRODUCT CHEMISTRY DATA ..... Reference 4

PROPOSED LABEL (5 COPIES) ..... Reference 5

TOXICOLOGY DATA ..... Reference 6

WAIVER REQUEST-TOXICOLOGY DATA REQUIREMENTS..... Reference 7

ECOLOGICAL EFFECTS DATA ..... Reference 8

WAIVER REQUEST-NON-TARGET ORGANISM AND
ENVIRONMENTAL EXPRESSION DATA REQUIREMENTS ..... Reference 9

EFFICACY DATA ..... Reference 10

CERTIFICATION WITH RESPECT TO CITATION OF DATA FORM ..... Reference 11

United States Department of Agriculture
Agricultural Research Service
Mid South Area Southern Regional Research Center
1100 Robert E. Lee Boulevard
P.O. Box 19687
New Orleans, Louisiana
70179-0687

Dr Janet Andersen
Biopesticide and Pollution Prevention Division
c/oDocument Processing Desk
Office of Pesticide Programs 7504C
U. S. Environmental Protection Agency
Room 226 , Crystal Mall 2
Arlington, Virginia 22202

July 30, 2002

RE: Aspergillus flavus AF-36
Section 3 registration

Dear Dr Andersen:

This letter authorizes the Environmental Protection Agency to refer to the USDA/ARS Southern Regional Research Center data on *Aspergillus flavus* when considering the application for registration for *Aspergillus flavus* AF-36 submitted for the Arizona Cotton Research and Protection Council by the IR-4 Project. This includes all data previously submitted for both the Experimental Use Permit and Section 3 registration.

Sincerely,

Peter J. Cotty, Ph.D.
Research Plant Pathologist

ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
3721 East Wier Avenue
Phoenix, Arizona 85040-2933
(602) 438-0059 - Phone
(602) 438-0407 - Fax

August 8, 2002

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266 A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Subject: Aspergillus flavus AF-36 Arizona Cotton Research and Protection Council Company Number 71693

Dear Dr. Andersen:

This letter authorizes the Environmental Protection Agency to refer to the Arizona Cotton Research and Protection Council data on Aspergillus flavus when considering the application for registration for Aspergillus flavus AF-36. This includes currently submitted data by USDA/ARS and the IR-4 Project in addition to data and waivers previously submitted for the Experimental Use Permit. We also authorize the IR-4 Project to act as our representative.

Sincerely,

Larry Antilla,
Director

Confidential Statement of Formula may be entitled to confidential treatment

Product Chemistry Data

Guideline 151-10, 151-11, 151-12, 151-13, 151-15, 151-16, 151-20, 151-21, 151-22, 151-25, 151-26

Please refer to the following volumes:

MRID Number and Title of Previously submitted Volumes

44626101 Cotty, P. ; Antilla , L. (1998) Aspergillus flavus isolate AF 36 -Analysis of samples, Certification of Ingredient limits, :Amendment Number 2 to MRID No. 43763402 .

44713701 Cotty, P. ; Antilla , L. (1998) Aspergillus flavus isolate AF 36 - Amended Manufacturing Process -- Amendment number 3.

44597001 Cotty, P. ; Antilla , L. (1998) Aspergillus flavus isolate AF 36 Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 to MRID 43763401

43763401 Cotty, P. (1995) Aspergillus flavus isolate AF 36 Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients.

43990001 Cotty, P. (1996) Aspergillus flavus isolate AF 36 Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No 1 to MRID 43763401.

43763402 Cotty, P. (1995) Aspergillus flavus isolate AF 36 Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits and Physical and Chemical Properties.

43972401 Cotty, P. (1995) Aspergillus flavus isolate AF 36 Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits Amendment No. 1 to MRID No. 43763404

Copy to Maureen Sherrill DA 8/14/2

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number: 279717

Application for Pesticide - Section I

1. Company/Product Number: 71693
2. EPA Product Manager: S. BACCHUS
3. Proposed Classification: [X] None [ ] Restricted
4. Company/Product (Name): ASPERGILLUS FLAVUS AF36
PM#
5. Name and Address of Applicant (Include ZIP Code)
Arizona Cotton Research & Protection Council
3721 E. Wier Avenue
Phoenix, Arizona 85040-2933
[X] Check if this is a new address
6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

[ ] Amendment - Explain below.
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[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Superceds previous submission dated June 26, 1998
Data (MRID) numbers from previous section 3 submission and Experimental Use Permit submission are cited.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging: [ ] Yes [X] No
* Certification must be submitted

Unit Packaging: [ ] Yes [X] No
If "Yes" Unit Packaging wgt. / No. per container

Water Soluble Packaging: [ ] Yes [X] No
If "Yes" Package wgt / No. per container

2. Type of Container: [ ] Metal [X] Plastic Bag [ ] Glass [ ] Paper [X] Other (Specify) Bulk Bags, Bulk Boxes

3. Location of Net Contents Information: [X] Label [ ] Container

4. Size(s) Retail Container: Plastic Bag: 50 lbs. Bulk Bag/Box: 1000-3000 lbs

5. Location of Label Directions: [X] On Label

6. Manner in Which Label is Affixed to Product: [X] Lithograph Paper glued Stenciled [ ] Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name: LARRY ANTILLA
Title: STAFF DIRECTOR
Telephone No. (Include Area Code): (602) 438-0059

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature: [signature]
3. Title: STAFF DIRECTOR
4. Typed Name: LARRY ANTILLA
5. Date: 8-8-02
6. Date Application Received: (Stamped)

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

White - EPA File Copy (original) Yellow - Applicant Copy

PRECAUTIONARY STATEMENTS
HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION

Potential dermal sensitizer. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Avoid breathing dust. Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling. Avoid contact with eyes and skin. See AGRICULTURAL USE DIRECTIONS for personal protection equipment.

ENVIRONMENTAL HAZARDS
Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water.

AGRICULTURAL USE DIRECTIONS
The pesticide should only be applied when the potential for drift to adjacent environmentally sensitive areas is minimal. May be applied to irrigated cotton fields.

RE-ENTRY STATEMENT
Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours. Personal protective equipment required for early entry workers are: Coveralls, longsleeved shirt, long pants, waterproof gloves, shoes plus socks, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

GENERAL USE PRECAUTIONS
Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.
PESTICIDE DISPOSAL: Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.
CONTAINER DISPOSAL: Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Returnable/Refillable Bulk Containers- Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

ASPERGILLUS FLAVUS AF36

FOR USE ONLY IN THE STATES OF ARIZONA AND TEXAS

FOR REDUCED AFLATOXIN CONTAMINATION OF COTTONSEED

ASPERGILLUS FLAVUS AF36 is a strain of *Aspergillus flavus* that occurs naturally on the cotton crop. When applied just prior to first bloom, ASPERGILLUS FLAVUS AF36 competes with strains of Aspergillus flavus that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop. Thus, ASPERGILLUS FLAVUS AF36 reduces the quantity of aflatoxin contaminating the crop.

Active ingredient: *Aspergillus flavus* strain AF36 (3,000 CFU/g)	0.0008%
Wheat seeds	99.9992%
Total:	100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT (First Aid)

IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration. Get medical attention.
IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration Number 69224
EPA Establishment Number 71093-AZ-001

Arizona Cotton Research and Protection Council
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

20-41-00

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

For application to cotton to control aflatoxin producing strains of *Aspergillus flavus*.

ASPERGILLUS FLAVUS AF36 has been shown to reduce aflatoxin contamination of cottonseed by competitively excluding aflatoxin producing fungi from the developing crop. This product is a living fungus growing on sterile wheat seed which serves as both a carrier and a nutrient source. After application and once the seed has been exposed to sufficient moisture (this usually occurs at irrigation) the fungus will grow out and the seed will be covered with green spores. The fungus growing out will appear first as a white fuzz and then as a green fuzz. These green spores will then be spread to the crop by wind and insects in the same manner that the aflatoxin producing fungi present in the field's soil are spread.

1. ASPERGILLUS FLAVUS AF36 may be applied through a cultivator mounted granular applicator to the surface of the soil under the plant canopy. DO NOT COVER THE GRANULES WITH SOIL.
2. The applicator should be adjusted to optimize delivery of ASPERGILLUS FLAVUS AF36 under the canopy and to minimize delivery of ASPERGILLUS FLAVUS AF36 to furrows.
3. ASPERGILLUS FLAVUS AF36 has been shown to be effective when applied in late May or early June, prior to first bloom. A single application should be made during the last cultivation before bloom.
4. For best results, the crop should be furrow irrigated with at least 2 inches of water within three days after application of ASPERGILLUS FLAVUS AF36.
5. Use 10 lbs of ASPERGILLUS FLAVUS AF36 per acre (per 13,000 linear feet based on 40 inch rows).

Aerial Application: Product may be applied by air at the specified rate. As with ground application, cultivation after application may diminish efficacy.

WARRANTY STATEMENT
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Toxicology Data

Please refer to the following volumes:

LIST OF STUDIES IN THE CURRENT SUBMISSION

VOLUME NO. AND TITLE

Volume 2 - Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat

Volume 3 - Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat -Interim Report.

Volume 4- Aspergillus flavus isolate AF 36 - Toxicity/ Pathogenicity to the Bob White Quail Avian Inhalation Test Tier 1.

Volume 5 - Honey bee Field Study of Aspergillus flavus AF36 in Cotton

Volume 7 - Aspergillus flavus isolate AF 36 - Hypersensitivity Incidents Amendment No. 1 to MRID 43972402, Amendment No. 2 to MRID 43763404

Also please refer to MRID Number and Title of Previously submitted Volumes

43972403 Shelton, L. (1996) Acute Oral Toxicity in Rats:Aspergillus flavus isolate AF 36

43972402 Cotty, P. (1996) Aspergillus flavus isolate AF 36 - Hypersensitivity Incidents With Microbial Pest Control Agents: Statement of Finding of No Hypersensitivity Amendment No. 1 to MRID 43763404

43763404 Cotty, P. (1995) Aspergillus flavus isolate AF 36 - Hypersensitivity Incidents With Microbial Pest Control Agents: Statement of Finding of No Hypersensitivity

Aspergillus flavus AF-36 - Waiver request for Toxicology Data Requirements, in regard to petition proposing an exemption from the requirements of a tolerance for Sorbitol Octanoate for use in All Food Commodities .

Section M Guidelines: 152-10, 152-11, 152-13, 152-14, 152-15, 152-16, 152-17, 152-18, 152-19, 152-20, 152-21, 152-22, 152-23, 152-24, 152-26, 152-29

We request a waiver of all the toxicology data mentioned in 40 CFR 158.690 that pertains to the following guidelines*:

Kind of Data Required	Terrestrial Food Crop	Guideline Reference No.
Acute dermal toxicity	R	152-11
Primary eye irritation	R	152-13
Primary dermal irritation	R	152-14
Hypersensitivity study	CR	152-15
Hypersensitivity incidents	CR	152-16
Studies to detect genotoxicity	R	152-17
Immune response	R	152-18
90-day feeding	CR	152-20
90-day dermal	CR	152-21
90-day inhalation	CR	152-22
Teratogenicity	CR	152-23
Mammalian mutagenicity	CR	152-19
Immune response	CR	152-24
Chronic exposure	CR	152-26
Oncogenicity	CR	152-29

* Refer to volumes previously submitted for Toxicology data waiver requests and the rationale for requesting a waiver for each of the data requirements.

Non Target Organism Data and
Environmental Fate Data

Please refer to the following volumes:

LIST OF STUDIES IN THE CURRENT SUBMISSION

VOLUME NO. AND TITLE

Volume 6 *Aspergillus flavus* isolate AF36 Non-target Organism and Environmental Safety Information

Also please refer to MRID Number and Title of Previously submitted Volumes

45307201 Cotty, P.. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus)

45307202 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Non -target Organism and Environmental Safety Information (Soil and Air Monitoring of Populations of A. flavus)

43763403 Cotty, P. , Hartman , C. (1995) Aspergillus flavus Isolate AF36: Safety Data in Support of Petition Proposing a Temporary Exemption from the Requiorements of Tolerance for Aspergillus flavus for use in Cotton Production

PRECAUTIONARY STATEMENTS
HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION

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ENVIRONMENTAL HAZARDS
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AGRICULTURAL USE DIRECTIONS
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GENERAL USE PRECAUTIONS
Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.
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Returnable/Refillable Bulk Containers- Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for foodfeed use, or for drinking water, bathing, or other human/animal uses.

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EPA Registration Number 69224
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs; 1000-3000 lbs

20-41-90

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WARRANTY STATEMENT
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PRECAUTIONARY STATEMENTS
HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION

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ENVIRONMENTAL HAZARDS
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AGRICULTURAL USE DIRECTIONS
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GENERAL USE PRECAUTIONS
Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

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CONTAINER DISPOSAL: Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
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EPA Registration Number 69224
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

20-41-90

Directions for Use

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PRECAUTIONARY STATEMENTS
HAZARD TO HUMAN AND DOMESTIC ANIMALS

CAUTION

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ENVIRONMENTAL HAZARDS
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STORAGE AND DISPOSAL

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NET CONTENTS: 50 lbs, 1000-3000 lbs

30-41-90

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1. ASPERGILLUS FLAVUS AF36 may be applied through a cultivator mounted granular applicator to the surface of the soil under the plant canopy. DO NOT COVER THE GRANULES WITH SOIL.
2. The applicator should be adjusted to optimize delivery of ASPERGILLUS FLAVUS AF36 under the canopy and to minimize delivery of ASPERGILLUS FLAVUS AF36 to furrows.
3. ASPERGILLUS FLAVUS AF36 has been shown to be effective when applied in late May or early June, prior to first bloom. A single application should be made during the last cultivation before bloom.
4. For best results, the crop should be furrow irrigated with at least 2 inches of water within three days after application of ASPERGILLUS FLAVUS AF36.
5. Use 10 lbs of ASPERGILLUS FLAVUS AF36 per acre (per 13,000 linear feet based on 40 inch rows).

Aerial Application: Product may be applied by air at the specified rate. As with ground application, cultivation after application may diminish efficacy.

WARRANTY STATEMENT
To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

Aspergillus flavus AF36 - Waiver request for Nontarget organism, date and expression data requirements in regard to petition proposing an exemption from the requirements of a tolerance for Sorbitol Octanoate for use in All Food Commodities production.

Section M Guidelines: 154-6, 154-7, 154-8, 154-9, 154-10, 154-11

We request a waiver of all the nontarget organism, fate and expression data requirements mentioned in 40 CFR 158.690 that pertain to the following guidelines:*

Kind of Data Required	Terrestrial Food Crop	Guideline Reference No.
Avian acute oral	R	154-6
Avian dietary	R	154-7
Freshwater fish LC_{50}	R	154-8
Freshwater invertebrate LC_{50}	R	154-9
Nontarget plant studies	CR	154-10
Nontarget insect testing	CR	154-11

Rationale for Waiver Request of Non-Target Organism
and Environmental Expression Data Requirements

1. Aspergillus flavus isolate AF36 is a naturally occuring strain of A. flavus. Documentation regarding the taxonomic position of that strain is presented in MRID No. 43763401.

2. Aspergillus flavus isolate AF36, a saprophytic fungus, is a normal constituent of the microflora in air and soil , and is found on living and dead plant material.throughout the world. Aspergillus flavus is particularly prominent in hot, dry climates supplemented with irrigation and is a ubiquitous component of the natural Arizona desert ecosystem. Quantities of A. flavus increase during crop production. A. flavus occurs widely on crop debris left in the soil. Refer to MRID No. 43763403, 45307201 and 45307202.

3. Hot dessert valleys of Arizona have the reputation of being the U.S. area with conditions most conductive to A. flavus. The result is perennially high levels of A. flavus on the commercial cottonseed crop. Aspergillus flavus isolate AF36 is already present on a broad segment of the U.S. cotton seed crop including Arizona and Texas and is a prominent part of the natural A. flavus community . Refer to MRID No. 43763403, 45307201 and 45307202.

4. Application of A. flavus AF36 does not increase the quantity of A. flavus either on the crop at maturity or in the soil one year after application. Refer to MRID No. 45307201 and 45307202.

5. The amount of A. flavus being added to the soil (10 lb of wheat seed containing 3,000 cfu/gram) is small in comparison to the amount of crop debris normally containing A. flavus that is added to the soil which includes cotton foliage, stalks, unharvested cottonseed(i.e. bolls that are missed during harvest and splillage, and gin trash which is often added back to the field and incorporated as organic matter.

6. A. flavus occurs widely on a wide range of crops including corn, wheat, rice, barley, peanuts, tree nuts, oilseeds and cottonseed. A. flavus is also common in livestock and poultry feed. Refer to MRID No. 43763403.

Efficacy Effects Data

Please refer to the following volume:

43763405 Cotty, P. Hartman, C. (1995) Aspergillus flavus Isolate AF36: Product Performance Data. USDA/ARS and IR-4.

Form Approved OMB No. 2070-0060

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

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Arizona Cotton Research and Protection Council, 3721 East Wier Avenue, Phoenix, Arizona 85040-2933 (602) 438-0059	EPA Registration Number/File Symbol 71693
Active Ingredient(s) and/or representative test compound(s) Aspergillus flavus AF-36	Date
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Cotton fields	Product Name Aspergillus flavus AF-36

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	5-8-02	LARRY ANTILLA - DIRECTOR

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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WASHINGTON, D.C. 20460

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DATA MATRIX

Date		EPA Reg No./File Symbol 71693	Page 1 of 4
Applicant's/Registrant's Name & Address	Arizona Cotton Research and Protection Council 3721 East Wier Avenue Phoenix, Arizona 85040-2933	Product AF-36	
Ingredient	Aspergillus flavus AF-36		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-10	Product Identity	43763401, 43990001	USDA/ARS	Own	
151-11	Manufacturing Process	43763401, 44597001, 44713701	AZ Cotton Research and Protection Council	Own	
151-12	Formulation of Unintentional Ingredients	43763401, 43990001	AZ Cotton Research and Protection Council	Own	
151-13	Analysis of Samples	43763402, 43972401, 44626101	AZ Cotton Research and Protection Council	Own	
151-15	Certification of Limits	43763402, 43972401, 44626101	AZ Cotton Research and Protection Council	Own	
151-16	Analytical Methods	43763402	AZ Cotton Research and Protection Council	Own	
151-17	Physical & Chemical Properties	43763402	AZ Cotton Research and Protection Council	Own	
152-10	Acute Oral	43972403	AZ Cotton Research and Protection Council	Own	
152-11	Acute Dermal	45307201	IR-4, Rutgers University	Exc 1	
152-12	Acute Inhalation	45307201	IR-4, Rutgers University	Exc 1	
152-13	Primary Eye Irritation	45307201	IR-4, Rutgers University	Exc 1	
152-14	Primary Dermal Irritation	45307201	IR-4, Rutgers University	Exc 1	
152-15	Hypersensitivity Incidents	43763404, 43972402	USDA/ARS	Own	
156A-2	Product Performance Data	43763405	USDA/ARS	Own	
154A-24	Honeybee Testing		AZ Cotton Research and Protection Council	Own	

Signature	Name and Title	Date
	Larry Antilla, Director	8-8-02

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DATA MATRIX

Date	EPA Reg No./File Symbol 71927-R	Page 2 of 4
Applicant's/Registrant's Name & Address: Arizona Cotton Research and Protection Council 3721 East Wier Avenue Phoenix, Arizona 85040-2933	Product: AF-36	

Ingredient: Aspergillus flavus AF-36

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			USDA/ARS	Own	
			AZ Cotton Research and Protection Council	Own	
			AZ Cotton Research and Protection Council	Own	
			AZ Cotton Research and Protection Council	Own	
			AZ Cotton Research and Protection Council	Own	
			AZ Cotton Research and Protection Council	Own	
			AZ Cotton Research and Protection Council	Own	
			AZ Cotton Research and Protection Council	Own	
			IR-4, Rutgers University	Exc 1	
			IR-4, Rutgers University	Exc 1	
			IR-4, Rutgers University	Exc 1	
			IR-4, Rutgers University	Exc 1	
			USDA/ARS	Own	
			USDA/ARS	Own	
			AZ Cotton Research and Protection Council	Own	

Signature	Name and Title	Date
	Larry Antilla, Director	8-8-02

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1 Waiver Requested

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DATA MATRIX

Date		EPA Reg No./File Symbol 71693	Page 3 of 4
Applicant's/Registrant's Name & Address	Arizona Cotton Research and Protection Council 3721 East Wier Avenue Phoenix, Arizona 85040-2933	Product AF-36	
Ingredient	Aspergillus flavus AF-36		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-17	Avian Inhalation		USDA/ARS	Own	
152-12	Acute Pulmonary Rat		USDA/ARS	Own	
154-16	Avian oral	45307201, 45307202	IR-4, Rutgers	Exc [1]	

Signature	Name and Title	Date
	Larry Antilla, Director	8-8-02

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1 Waiver Requested

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DATA MATRIX

Date	EPA Reg No./File Symbol 71693	Page 4 of 4
Applicant's/Registrant's Name & Address: Arizona Cotton Research and Protection Council 3721 East Wier Avenue Phoenix, Arizona 85040-2933	Product: AF-36	

Ingredient: Aspergillus flavus isolate AF-36

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			USDA/ARS	Own	
			USDA/ARS	Own	
			IR-4, Rutgers	Exc	

Signature	Name and Title	Date
[signature]	Larry Antilla, Director	5-8-02

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→ 006456 ai #

2E6497 under already. October 29, 2002

45739100 Interregional Research Project No. 4 (2002) Submission of Toxicity and Exposure Data in Support of the Petition for Tolerance of Aspergillus flavus on Cotton. Transmittal of 4 Studies.

SUBMITTED IN SUPPORT OF: ~~2E6497~~ Cancel

Sec 3

45739103 Smith, D.; Cotty, P.; Braverman, M.; et al. (2002) Aspergillus flavus Isolate AF36: Non-Target Organism and Environmental Safety Information: Lab Project Number: IR-4 PR NO.52B: Unpublished study prepared by Soil & Crop Sciences, Southern Regional Research Center USDA/ARS, Rutgers University and Arizona Cotton Research and Protection Counsil. 57 p.

SUBMITTED IN SUPPORT OF: ~~2E6497~~ Cancel

152-32

45739101 Blanchard, E.; Carter, J. (2002) Aspergillus flavus AF36: Acute Pulmonary Toxicity and Pathogenicity to the Rat: Interim Report: Lab Project Number: UAR/006. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 86 p. {OPPTS 885.3150}

SUBMITTED IN SUPPORT OF: ~~2E6497~~ Cancel

152-37

45739104 Antilla, L.; Cotty, P.; Braverman, M. (2002) Aspergillus flavus Isolate AF336: Hypersensitivity Incidents: Lab Project Number: 52B. Unpublished study prepared by Arizona Cotton Research and Protection Council, Southern Regional Research Center and Rutgers University. 18 p.

SUBMITTED IN SUPPORT OF: 2E6497

154-24

Sec 3

45739102 Mayer, D. (2001) Honey Bee Field Study of Aspergillus flavus AF36 in Cotton: Lab Project Number: WSU 00-011. Unpublished study prepared by Washington State University. 30 p. {OPPTS 850.3040, 885.4380}

SUBMITTED IN SUPPORT OF: 2E6497

7/30/02 AF 36 Telecon w Peter Cotty
Mike Braverman

Sec 13

wt of spores added to wheat when colonized.

can't detect spores

cfu

viable propagules/

no significant sporulation on wheat

grow spores on wheat for 24 hours

dry wt amt of spores

CW 0.01% – 0.5% by wt [cfu/gm]

method to determine [wt of spores/wt of wheat]

→ 5 batch analyses

fresh spores on day of inoculation

use turbidometry (cfu/gm) for inoculum on wheat

amt of inoculum – 2.5 L spores/

amt of wheat –

EP capable of producing $10^5 \times 10^9$ spores	① Correct turbidity w cfu
	②

measure spores – dry spores.

① Viability

② 5 batch

Mike Braverman
<braverman@AESOP.
RUTGERS.EDU>

07/27/02 11:24 PM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Phil Hutton/OC/USEPA/US@EPA, Peter Cotty
<pjcotty@srrc.ars.usda.gov>, John Kough/DC/USEPA/US@EPA
Subject: RE: AF36

Shanaz

1 PM EST is OK for me. Since you are asking for a phone number I assume you would be able to call me. Is that right?

I am at the American Phytopathological Society Meetings in Milwaukee. I am at the Hilton Milwaukee City Center.
(414)271-7250 room 1420.

Thanks

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

HH 414-271-7250 Rm 1420
504-256 U341

-----Original Message-----
From: Bacchus.Shanaz@epamail.epa.gov
[mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Thursday, July 25, 2002 12:08 PM
To: Mike Braverman
Cc: Phil Hutton; Peter Cotty; Kough.John@epamail.epa.gov
Subject: RE: AF36

Mike, Peter:
Are you available next Tues, July 30 at 1 p.m. EST for the teleconference you requested to discuss the expression of the ai on the label? It shouldn't take too long. I'll try to get Phil and John Kough (I know at least Phil will be available). We can use Phil's phone 703-308-8260 and as far as I can remember, we can call 2 different #s. Do let us know what phone #s we should call.

After that Phil's on vacation so then we can talk in August. Phil, when do you get back in August?
Looking forward to hearing from you,
Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

Peter Cotty
<pjcotty@srrc.ars.usda.gov>
07/29/02 09:19 AM

To: braverman@AESOP.RUTGERS.EDU, Shanaz Bacchus/DC/USEPA/US@EPA
cc: Phil Hutton/DC/USEPA/US@EPA, John Kough/DC/USEPA/US@EPA
Subject: RE: AF36

Shanaz,

Tuesday, July 30th at 1 PM EST is fine with me. My number is 504-286-4391.

Thank you.

--Peter.

Peter J. Cotty, Ph.D.
Research Plant Pathologist
Southern Regional Research Center
Agricultural Research Service
United States Department of Agriculture
1100 Robert E. Lee Blvd.
New Orleans, LA 70124

pjcotty@srrc.ars.usda.gov
Phone: 504-286-4391
FAX: 504-286-4496

>>> <Bacchus.Shanaz@epamail.epa.gov> 07/25/02 11:07AM >>>

Mike, Peter:
Are you available next Tues, July 30 at 1 p.m. EST for the teleconference you requested to discuss the expression of the ai on the label? It shouldn't take too long. I'll try to get Phil and John Kough (I know at least Phil will be available). We can use Phil's phone 703-308-8260 and as far as I can remember, we can call 2 different #s. Do let us know what phone #s we should call.

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Looking forward to hearing from you,
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USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

Shanaz Bacchus

07/30/02 10:01 AM

To: Peter Cotty <pjcotty@srrc.ars.usda.gov>
cc: braverman@AESOP.RUTGERS.EDU, Phil Hutton/DC/USEPA/US@EPA, Carl Etsitty/DC/USEPA/US@EPA, Chris Wozniak/DC/USEPA/US@EPA
Subject: RE: AF36

Tues 7/30 @ 1 p.m. is good for Carl Etsitty, Chris Wozniak and me. Phil is it a good time for you to discuss the units of expression of AF36 on the CSF and label? I have the phone numbers Peter and Mike sent for the teleconference.

shawn
Phone: 703-308-8097
Fax: 703-308-7026
Peter Cotty <pjcotty@srrc.ars.usda.gov>

Peter Cotty
<pjcotty@srrc.ars.usda.gov>

07/29/02 09:t9 AM

To: braverman@AESDP.RUTGERS.EDU, Shanaz Bacchus/DC/USEPA/US@EPA
cc: Phil Hutton/DC/USEPA/US@EPA, John Kough/DC/USEPA/US@EPA
Subject: RE: AF36

Shanaz,

Tuesday, July 30th at 1 PM EST is fine with me. My number is 504-286-4391.

Thank you.

--Peter.

Peter J. Cotty, Ph.D.
Research Plant Pathologist
Southern Regional Research Center
Agricultural Research Service
United States Department of Agriculture
1100 Robert E. Lee Blvd.
New Orleans, LA 70124

pjcotty@srrc.ars.usda.gov
Phone: 504-286-4391
FAX: 504-286-4496

>>> <Bacchus.Shanaz@epamail.epa.gov> 07/25/02 11:07AM >>>

Mike, Peter:
Are you available next Tues, July 30 at 1 p.m. EST for the teleconference you requested to discuss the expression of the ai on the label? It shouldn't take too long. I'll try to get Phil and John Kough (I know at least Phil will be available). We can use Phil's phone 703-308-8260 and as far as I can remember, we can call 2 different #s. Do let us know what phone #s we should call.

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Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

Section 3 EUP

71693-R ← 69224-EUP-1

8E5001 ← 5E0575

006456 / 8

44597000 Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerance of Aspergillus flavus isolate AF36 in/on Wheat. Transmittal of 1 Study.

SUBMITTED IN SUPPORT OF: 8E5001

44713700 Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerances of Aspergillus flavus in/on Cotton. Transmittal of 1 Study.

SUBMITTED IN SUPPORT OF: 8E5001
SUBMITTED IN SUPPORT OF: 5E4575
SUBMITTED IN SUPPORT OF: 069224EX1

151-11
44713701 Cotty, P.; Antilla, L. (1998) Aspergillus Flavus isolate AF36--Amended Manufacturing Process--Amendment No.3: Lab Project Number: 52B. Unpublished study prepared by IR-4. 21 p.

SUBMITTED IN SUPPORT OF: 8E5001
SUBMITTED IN SUPPORT OF: 5E4575
SUBMITTED IN SUPPORT OF: 069224EX1

151-20
151-21
151-22
151-25
44597001 Cotty, P.; Antilla, L. (1998) Aspergillus flavus Isolate AF36 Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 MRID 43763401: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, Arizona Cotton Research and Protection Council and Rutgers Univ. 38 p.

SUBMITTED IN SUPPORT OF: 8E5001

Put in
Jacket
71693-R

006456

43972400 Interregional Research Project No. 4 (1996) Submission of Product Analysis and Toxicology Data in Support of an Experimental Use Permit for Aspergillus flavus AF36. Transmittal of 3 Studies.

SUBMITTED IN SUPPORT OF: 069224EX1

43990000 Interregional Research Project No. 4 (1996) Submission of Product Chemistry Data in Support of the Application for Experimental Use Permit for Apergillus flavus AF36. Transmittal of 1 Study.

SUBMITTED IN SUPPORT OF: 069224EX1

44713700 Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerances of Aspergillus flavus in/on Cotton. Transmittal of 1 Study.

SUBMITTED IN SUPPORT OF: 8E5001
SUBMITTED IN SUPPORT OF: 5E4575
SUBMITTED IN SUPPORT OF: 069224EX1

45307200 USDA/ARS Southern Regional Research Center (2001) Submission of Environmental Fate Data in Support of the Petition for Tolerance of Aspergillus flavus Isolate AF36/Cotton in/on Cotton. Transmittal of 2 Studies.

SUBMITTED IN SUPPORT OF: 5E4575
SUBMITTED IN SUPPORT OF: 069224EX1

45307202 Cotty, P. (2001) Aspergillus flavus Isolate AF36 Non-target Organism and Environmental Safety Information (Soil and Air Monitoring of Populations of A. flavus): Lab Project Number: 52B. Unpublished study prepared by Interregional Research Project No.4. 130 p.

SUBMITTED IN SUPPORT OF: 5E4575
SUBMITTED IN SUPPORT OF: 069224EX1

45307202 Cotty, P. (2001) Aspergillus flavus Isolate AF36 Non-target Organism and Environmental Safety Information (Soil and Air Monitoring of Populations of A. flavus): Lab Project Number:

52B. Unpublished study prepared by Interregional Research Project No.4. 130 p.

SUBMITTED IN SUPPORT OF: 5E4575
SUBMITTED IN SUPPORT OF: 069224EX1

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus): Lab Project Number: 52B. Unpublished study prepared by Interregional Research Project No.4. 130 p.

SUBMITTED IN SUPPORT OF: 5E4575
SUBMITTED IN SUPPORT OF: 069224EX1

43763403 Cotty, P.; Hartman, C. (1995) Aspergillus flavus Isolate AF36--Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirements of a Tolerance for Aspergillus flavus for Use in Cotton Production: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 882 p.

SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

43763405 Cotty, P.; Hartman, C. (1995) Aspergillus flavus Isolate AF36: Product Performance Data: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 145 p.

SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

43763400 USDA/ARS and IR-4 (1995) Submission of Product Chemistry, Toxicity, and Risk Data in Support of an Experimental Use Permit for Aspergillus flavus AF36. Transmittal of 5 Studies.

SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

151-15
151-10
151-13
44626101 Cotty, P.; Antilla, L. (1998) Aspergillus flavus isolate AF36-Analysis of Samples, Certification of Ingredient Limits,

Analytical Methods for Certified Limits: Amendment No. 2 to MRID No. 43763402: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, and Arizona Cotton Research and Protection Council. 33 p.

SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

151-11
44713701 Cotty, P.; Antilla, L. (1998) Aspergillus Flavus isolate AF36--Amended Manufacturing Process--Amendment No.3: Lab Project Number: 52B. Unpublished study prepared by IR-4. 21 p.

SUBMITTED IN SUPPORT OF: 8E5001
SUBMITTED IN SUPPORT OF: 5E4575
SUBMITTED IN SUPPORT OF: 069224EX1

151-20
43990001 Cotty, P. (1996) Aspergillus flavus Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process, and Discussion on the Formation of Unintentional Ingredients: Amendment No. 1 to MRID 43763401: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS, Southern Regional Research Center. 6 p.

SUBMITTED IN SUPPORT OF: 069224EX1

151-20
151-21
151-22
43763401 Cotty, P. (1995) Aspergillus flavus Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 85 p.

SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

151-25
151-20
151-26

43763402 Cotty, P. (1995) Aspergillus flavus Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits, and Physical and Chemical Properties: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 8 p.

SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

151-21
43972401 Cotty, P. (1996) Aspergillus flavus Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits: Amendment No. 1 to MRID No. 43763404: Lab Project Number: PR 52B: 52B. Unpublished study prepared by Southern Regional Research Center, USDA/ARS. 6 p.

SUBMITTED IN SUPPORT OF: 069224EX1

152-30
43972403 Shelton, L. (1996) Acute Oral Toxicity Study in Rats: (Aspergillus flavus AF36): Final Report: Lab Project Number: M96AG84.6G31: MA M96AG84.6G31. Unpublished study prepared by Microbiological Associates, Inc. 59 p.

SUBMITTED IN SUPPORT OF: 069224EX1

152-37
43972402 Cotty, P. (1996) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents with Microbial Pest Control Agents: Statement of Finding of No Hypersensitivity: Amendment No. 1 to MRID No. 43763404: Lab Project Number: 52B: PR 52B. Unpublished study prepared by Southern Regional Research Center, USDA/ARS. 4 p.

SUBMITTED IN SUPPORT OF: 069224EX1

152-37
43763404 Cotty, P. (1995) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents with Microbial Pest Control Agents: Statement of Finding No Hypersensitivity: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 4 p.

SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

006456

44626100 Interregional Research Project No. 4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerance of Aspergillus flavus isolate AF36 in/on Cotton. Transmittal of 1 Study.

SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

44713700 Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerances of Aspergillus flavus in/on Cotton. Transmittal of 1 Study.

SUBMITTED IN SUPPORT OF: 8E5001
SUBMITTED IN SUPPORT OF: 5E4575
SUBMITTED IN SUPPORT OF: 069224EX1

45307200 USDA/ARS Southern Regional Research Center (2001) Submission of Environmental Fate Data in Support of the Petition for Tolerance of Aspergillus flavus Isolate AF36/Cotton in/on Cotton. Transmittal of 2 Studies.

SUBMITTED IN SUPPORT OF: 5E4575
SUBMITTED IN SUPPORT OF: 069224EX1

45307202 Cotty, P. (2001) Aspergillus flavus Isolate AF36 Non-target Organism and Environmental Safety Information (Soil and Air Monitoring of Populations of A. flavus): Lab Project Number: 52B. Unpublished study prepared by Interregional Research Project No.4. 130 p.

SUBMITTED IN SUPPORT OF: 5E4575
SUBMITTED IN SUPPORT OF: 069224EX1

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus): Lab Project Number: 52B. Unpublished study prepared by Interregional Research Project No.4. 130 p.

SUBMITTED IN SUPPORT OF: 5E4575
SUBMITTED IN SUPPORT OF: 069224EX1

43763403 Cotty, P.; Hartman, C. (1995) Aspergillus flavus Isolate

AF36--Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirements of a Tolerance for Aspergillus flavus for Use in Cotton Production: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 882 p.

SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

43763405 Cotty, P.; Hartman, C. (1995) Aspergillus flavus Isolate AF36: Product Performance Data: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 145 p.

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151-25
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SUBMITTED IN SUPPORT OF: 069224EX1
SUBMITTED IN SUPPORT OF: 5E4575

Form Approved OMB No. 2070-0060

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

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date		EPA Reg No./File Symbol 71693 — R	Page 1 of 4
Applicant's/Registrant's Name & Address	Arizona Cotton Research and Protection Council 3721 East Wier Avenue Phoenix, Arizona 85040-2933	Product AF-36	

Ingredient Aspergillus flavus AF-36

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-~~10~~ 20	Product Identity	43763401, 43990001	USDA/ARS	Own	
151-~~11~~ 21	Manufacturing Process	43763401, 44597001, 44713701	AZ Cotton Research and Protection Council	Own	
151-12	Formulation of Unintentional Ingredients	43763401, 43990001	AZ Cotton Research and Protection Council	Own	
151-13	Analysis of Samples	43763402, 43972401, 44626101	AZ Cotton Research and Protection Council	Own	
151-15	Certification of Limits	43763402, 43972401, 44626101	AZ Cotton Research and Protection Council	Own	
151-16	Analytical Methods	43763402	AZ Cotton Research and Protection Council	Own	
151-17	Physical & Chemical Properties	43763402	AZ Cotton Research and Protection Council	Own	
152-~~10~~ 30	Acute Oral	43972403	AZ Cotton Research and Protection Council	Own	
152-11	Acute Dermal	45307201	IR-4, Rutgers University	Exc	
152-12	Acute Inhalation	45307201	IR-4, Rutgers University	Exc	
152-13	Primary Eye Irritation	45307201	IR-4, Rutgers University	Exc	
152-14	Primary Dermal Irritation	45307201	IR-4, Rutgers University	Exc	
152-15	Hypersensitivity Incidents 45739104	43763401, 43972402	USDA/ARS	Own	
156A-2	Product Performance Data	43763405	USDA/ARS	Own	
154A-24	Honeybee Testing cpl. 2/96	457391-02	AZ Cotton Research and Protection Council	Own	

Signature [signature]

Name and Title Larry Antilla, Director

Date 8-8-02

EPA Form 8570-35 (9-97) Electronic and Paper versions available. S[illegible] only Paper version.

Agency Internal Use Copy

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

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date

EPA Reg No./File Symbol 71693 R

Applicant's/Registrant's Name & Address: Arizona Cotton Research and Protection Council 3721 East Wier Avenue Phoenix, Arizona 85040-2933

Product: AF-36

Ingredient: Aspergillus flavus AF-36

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-17	Avian Inhalation Powers not passed	45739103	USDA/ARS	Own	
152-12	Acute Pulmonary Rat mg	45739101	USDA/ARS	Own	
154-16	Avian oral	45307201, 45307202	IR-4, Rutgers	Exc [1]	

Signature

Name and Title: Larry Antilla, Director

Date: 8-8-02

EPA Form 8570-35 (5-97) Electronic and Paper versions available. Only Paper version.

1 Waiver Requested

Agency Internal Use Copy

457391-00

Interregional Research Project No. 4
Center for Minor Crop Pest Management

August 12, 2002

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk (IR4)
266A Crystal Mall No. 2
1921 Jefferson Davis Highway
Arlington, VA 22202

BIOPESTICIDE PROPOSAL

~~2E4497~~ To 8E5001

RE: Aspergillus flavus AF-36/Tolerance Exemption for cotton
RAL: Shanaz Bacchus (703)308-8097

Dear Janet:

The undersigned, Dr. W.L. Biehn, Interregional Research Project No. 4, The Technology Centre of New Jersey, 681 U.S. Highway #1 South, North Brunswick, New Jersey 08902-3390, on behalf of the IR-4 Project submit this petition pursuant to Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the microbial biopesticide, Aspergillus flavus AF-36.

List of Studies Submitted in Support of Proposed Exemption from the Requirements of a Tolerance for Aspergillus flavus AF-36.

Volume No. and Title

Volume 1- Petition Proposing An Exemption from the Requirement of a Tolerance For Sorbitol Octanoate for use in All Food Crops ADMIN

Volume 2 - Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat REJ (02)

Volume 3 - Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat -Interim Report. 45739101

Volume 4- Aspergillus flavus isolate AF 36 - Toxicity/ Pathogenicity to the Bob White Quail Avian Inhalation Test Tier 1. REJ (04)

Volume 5 - Honey bee Field Study of Aspergillus flavus AF36 in Cotton 45739102

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

Janet Andersen (con't)

Volume 6 Aspergillus flavus isolate AF36 Non-target Organism and Environmental Safety Information 45739103

Volume 7 - Aspergillus flavus isolate AF 36 - Hypersensitivity Incidents Amendment No. 1 to MRID 43972402, Amendment No. 2 to MRID 43763404 45739104

List of Supplemental Information Submitted in Support of this Petition:

1. Notice of Filing*
2. Letter of Authorization

* Notice of Filing is also being provided electronically , in Word Perfect format, under separate cover.

Yours very truly,

Michael Braverman

Interregional Research Project No. 4
Petitioner

Per_____
IR-4 Project Coordinator
IR-4 Project
Rutgers, The State University of New Jersey
The Technology Centre of New Jersey
681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390

Mike Braverman
<braverman@AESOP.RUTGERS.EDU>
10/31/02 10:13 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA
cc: Peter Cotty <pjcotty@srrc.ars.usda.gov>, Phil Wakelyn <pwakelyn@cotton.org>, Phil Hutton/DC/USEPA/US@EPA
Subject: RE: Aspergillus flavus AF36 submissions

Shanaz

Some of the older letters from the front end desk are not marked as toward PP number so I decided to organize the information you reqested into a table which divides new and previously submitted volumes.

I have organized the relationship between PP numbers and MRID numbers in the attached file. The titles connected to the previously submitted volumes and their associated MRID numbers can also be found in the Registration Vol of the 8-12-02 submission. In addition they are organized by Guideline number in the Registartion volume of 8-12-02 in the data matrix table

If you detect any differences between these numbers and those in your PRATS system please let me know.

As noted, for the last 2 PP numbers I do not have MRID numbers for the rejected volumes 2 and 4 for which I have sent corrected compliance statements and the last PP number 2E6511 must relate to the last submission of 1 volume. I have not received an 86-5 compliance letter for the Sept 12 submission

In summary there are only 8 new volumes that have been submitted as follows:

Submitted 8-12-02
71693-R/2E6497

Volume 1- Aspergillus flavus isolate AF36/ Tolerance Exemption in or on Cotton
ADMIN VOL

Volume 2 - Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat
REJECTED VOLUME

Volume 3 - Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat -Interim Report.
MRID 45739101

Volume 4- Aspergillus flavus isolate AF 36 - Toxicity/ Pathogenicity to the Bob White Quail Avian Inhalation Test Tier 1. REJECTED VOLUME

Volume 5 - Honey bee Field Study of Aspergillus flavus AF36 in Cotton.
MRID 45739102

Volume 6 Aspergillus flavus isolate AF36 Non-target Organism and Environmental Safety Information
MRID 45739103

Volume 7 - Aspergillus flavus isolace AF 36 - Hypersensitivity Incidents Amendment No. 1 to MRID 43972402, Amendment No. 2 to MRID 43763404.
THIS volume-MRID 45739104

Submitted 9-12-02

2E6511? MRID?

Volume 1- Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat

If you need any other information to facilitate review of the new data let me know. Look forward to seeing you on Nov 7th

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu
IR-4 Website www.cook.rutgers.edu/~ir4

-----Original Message-----
From: Bacchus.Shanaz@epamail.epa.gov
(mailto:Bacchus.Shanaz@epamail.epa.gov]
Sent: Thursday, October 24, 2002 10:46 AM
To: braverman@AESOP.RUTGERS.EDU
Subject: Aspergillus flavus AF36 submissions

1. Do you have among your records any list of MRID #s from our front desk in connection with the submissions:

71693-R
8E5001
2E6497
2E6511

If so, please fax them to my attention at 703-308-7026. I need to coordinate the activities on the EUP with those of the Section 3 registration, in order to have an efficient review of the new data only.

2. Regarding Phil Wakelyn's request for a meeting, do you have an agenda? If so, please send it. Gail cannot attend the November 7 meeting. What does your group's schedule look like on Nov. 19, 20, 21? If you have any questions, do not hesitate to email me.

Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

AF36MRID.wpd

AF-36 PREVIOUS SUBMISSIONS			NEW SUBMISSIONS	
069224EX1	5E4575	8E5001	71693-R/2E6495	~~2E6511~~ not in PDMS
43763400	43763400	44597000	Vol2 *	Vol 1**
43763401	43763401	44597001	45739101	
43763402	43763402	44713700	Vol 4*	
43763403	43763403	44713701	45739102	
43763404	43763404		45739103	
43763405	43763405		45739104	
43977400	44626100			
43972401	44626101			
43972402	44713700			
43972403	44713701			
43990000	45307200			
43990001	45307201			
44626100	45307202			
44626101				
44713700				
44713701				
45307200				
45307201				
45307202				

*- These volumes were rejected by front end desk during 86-5 screening because of no signature from sponsor and submitter on compliance statement. This has been corrected but I have not received an MRID number.

**- I do not have any information or any MRID number associated with PP 2E6511. Considering that this PP number is later in sequence I assume it is related to a submission on 9-12-02 which was one volume containing the last rat pulmonary study with physiological saline(Note: The first pulmonary rat study with Tween 80 is the rejected Volume 2 , the second pulmonary rat study with physiological saline is interim report MRID 45739101 and this is the third pulmonary rat study)

Who owns data.

AF-36 PREVIOUS SUBMISSIONS			NEW SUBMISSIONS	
069224EX1	**5E4575**	**8E5001**	**71693-R/2E6497**	**2E6511**
43763400	43763400	44597000	Vol2 *	Vol 1**
43763401	43763401	44597001	45739101	
43763402	43763402	44713700	Vol 4*	
43763403	43763403	44713701	45739102	
43763404	43763404		45739103	
43763405	43763405		45739104	
43977400	44626100			
43972401	44626101			
43972402	44713700			
43972403	44713701			
43990000	45307200			
43990001	45307201			
44626100	45307202			
44626101				
44713700				
44713701				
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45307202				

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P. Hutton

BPPD PRAT ACTION CODING FORM

PM 90: Janet Andersen

006456 PC CODE

REGISTRANT/COMPANY NAME: IR4

Fast Track: Yes☐ No☐
Reviewer BACCHUS
Assigned by POLK

EPA REG./FILE SYMBOL ~~2E6511~~

ACTION CODE ~~210~~ 200

[Note: If Fast Track, you may need to change Reviewer's Name in PRAT.]

(New A.I/EUP'S/Tolerances: Yes☐ No☐)

DATE OF APPLICATION 9/12/02

EPA RECEIVED DATE 9/17/02

BPPD RECEIVED DATE 10/04/02

SUBMISSION BARCODE S623260

ASSIGNED IN PRAT: Yes☒ No☐

COMPLETED BY T. Bethea DATE 10/11/02

LOGGED IN BRATS: Yes☑ No☐ DATE 10/16 COMPLETED BY [illegible]

RAL RECEIVED _____ DATE _____
(RAL initials)

Belong to ~~2E6477~~ 8E5001

Mitasent P3 per 86-5

FINAL ACTION

RESPONSE CODE: _____

RESPONSE DATE: _____

MOS: _____ (1) Cite All
_____ (4) Not Applicable
_____ (8) Selective

CRP	Yes☐	No☐
Restricted Use:	Yes☐	No☐
Manufacturing Use:	Yes☐	No☐
Exclusive Use:	Yes☐	No☐

Took To Teresa Downs 11/5/02

acute polar rat

REJ Need p3

Whooms data?

- E merg exemption Impt/Exp.
- F Food/Feed
- G Temp. Eff
- H Food additive

BPPD

This an ACCEPTED submission

This is a PARTIALLY ACCEPTED COMPLETELY REJECTED submissio

United States Environmental Protection Agency
Office of Pesticide Programs
Information Resources and Services Division
Information Services Branch

9-24-02

EPA

ADMINISTRATIVE NO(S).: 2E6511

PM: 90 Janet Andersen

CHEMICAL NO.:

The jacket for this action can be requested through the JACKETS system.

SEP 27 2002

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

INTERREGIONAL RESEARCH PROJECT NO. 4
TECHNOLOGY CENTRE OF N.J.
681 U.S. HIGHWAY #1 SOUTH
NORTH BRUNSWICK, NJ 089023390

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 09/17/02. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected study [01] :

A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40 CFR160 is required for all studies (except range finding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

Resend
OK

Interregional Research Project No. 4
Center for Minor Crop Pest Management

FAX

From: Michael Braverman

To: Shanaz Bacchus

FAX: 703-308-~~8097~~ 7026

Date: 11

Number of pages including cover page? 5

Thanks for faxing the 86-5 letter of the 9/12/02 submission date.
I assumed that this would be rejected because it had the same problem as Vol 2 and 4 of the 8/12/02 submission.
I already had Peter sign the page 3 - attached Thanks - Micha.

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

SEP 27 2002

INTERREGIONAL RESEARCH PROJECT NO. 4
TECHNOLOGY CENTRE OF N.J.
681 U.S. HIGHWAY #1 SOUTH
NORTH BRUNSWICK, NJ 089023390

Report of Analysis for Compliance with PR Notice 86-5

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Post-it® Fax Note 7671	Date 11/1/02	# of pages ▶ 3
To Mike Braverman	From Thomas Bacelis	
Co./Dept. USDA/IR-4	Co. EPA/OPP/BPPD	
Phone # 732-932-9575	Phone # 703-308-8097	
Fax # 732-932-8481	Fax # 703-308-7026	

2E6511
8E5001
ai# 006456

Interregional Research Project No. 4
Center for Minor Crop Pest Management

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk (IR4)
266A Crystal Mall No. 2
1921 Jefferson Davis Highway
Arlington, VA 22202

BIOPESTICIDE PROPOSAL

Sept. 12, 2002

RE: Aspergillus flavus AF-36/Tolerance Exemption for cotton
RAL: Shanaz Bacchus (703)308-8097

Dear Janet:

The undersigned, Dr. Michael Braverman, Interregional Research Project No. 4, The Technology Centre of New Jersey, 681 U.S. Highway #1 South, North Brunswick, New Jersey 08902-3390, on behalf of the IR-4 Project submit this petition pursuant to Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the microbial biopesticide, Aspergillus flavus AF-36.

List of Studies Submitted in Support of Proposed Exemption from the Requirements of a Tolerance for Aspergillus flavus AF-36.

Volume No. and Title
eject (01) Volume 1- Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat

Note: Although this volume is being submitted individually, it is the third volume pertaining to studies on ASPERGILLUS FLAVUS AF36 ACUTE PULMONARY TOXICITY AND PATHOGENICITY TO THE RAT.

In a previous submission (August 12, 2002) two volumes (Volume 2 of 7 and Volume 4 of 7) were submitted but no MRID numbers have been assigned yet.

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

Janet Andersen (con't)

List of Supplemental Information Submitted in Support of this Petition:

1. Notice of Filing*
2. Letter of Authorization

* Notice of Filing has already been provided electronically , in Word Perfect format.

Yours very truly,

Michael Bruenman

Interregional Research Project No. 4
Petitioner

Per_____
IR-4 Project Coordinator
IR-4 Project
Rutgers, The State University of New Jersey
The Technology Centre of New Jersey
681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390

CC; Peter Cotty, Larry Antilla

UAR 006/023279/AC

COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

The study described in this report was conducted in compliance with the following Good Laboratory Practice standards and, with the exceptions noted below, I consider the data generated to be valid.

The UK Good Laboratory Practice Regulations 1999 (Statutory Instrument No. 3106).

OECD Principles of Good Laboratory Practice (as revised in 1997), ENV/MC/CHEM(98)17.

EC Commission Directive 1999/11/EC of 8 March 1999 (Official Journal No. L 77/8).

Information regarding test substance characterisation, namely batch/lot number and expiry date, was not made available to Huntingdon Life Sciences as required for compliance with Good Laboratory Practice Standards given above.

Chemical analysis of formulated test articles for determination of stability and homogeneity was not undertaken for this study.

.....
Emma L. Blanchard, B.Sc. (Hons.),
Study Director,
Huntingdon Life Sciences Ltd.

.....
Date

Peter J. Cotty, Ph.D.
USDA/ARS
Study Sponsor

Sept. 20, 2002
Date

Peter J. Cotty, Ph.D.
USDA/ARS
Submitter

Sept. 20, 2002
Date

Rejected

(01)

Studies

Shanaz Bacchus
10/23/02 03:45 PM

To: Phil Hutton/DC/USEPA/US@EPA
cc: Janet Andersen/DC/USEPA/US@EPA
Subject: Aspergillus flavus AF36

FYI
---- Forwarded by Shanaz Bacchus/DC/USEPA/US on 10/23/02 03:43 PM ----

Shanaz Bacchus
10/23/02 03:43 PM

To: John Jamula/DC/USEPA/US@EPA, Teresa Downs/DC/USEPA/US@EPA
cc:
Subject: Aspergillus flavus AF36

A. flavus AF36 was a new active ingredient in an EUP for the last 6 years during which time the applicant was generating efficacy data to support the claim for aflatoxin control in cotton. I am trying to sort out their data submissions which have been piece meal. Because of this, they may have been given more than 1 petition #, and data for the registration may have been submitted for the petition, whereas it should have been linked to the registration #. The applicant is new at the process and somewhat confused.

To help me sort out the confusions, can you do an electronic bibliography, by guideline, for me on the following:

1. active ingredient # 006456
2. 69224- EUP-1
3. 71693-R
4. **PP#** 2E6497
5. **PP# 5E4575**
6. **PP#** 2E6511

I figure that the search by ai # will show me if there is another petition # associated with the submissions....is that a correct assumption?
If you have any questions, do not hesitate to call/email me.
Thanks for your help.
Sincerely
Shanaz Bacchus, Chemist
USEPA/OPP (Mail Code 7511C)
Biopesticides and Pollution Prevention Division
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460
Phone: 703-308-8097
Fax: 703-308-7026

Teresa
Check Rejected study
Do you want study sponsor + submitter on same page

Aspergillus flavus AF36 (pc 006456 bib502.wpd) run date: 5/30/02

43763400 USDA/ARS and IR-4 (1995) Submission of Product Chemistry, Toxicity, and Risk Data in Support of an Experimental Use Permit for Aspergillus flavus AF36. Transmittal of 5 Studies.

	SBMTR	SBMSN	DATE	ADMIN-NR	ACCSN	SFX
01 OF 02	069224		08/09/95	069224-EX1	437634	00
02 OF 02	069224		08/09/95	5E4575-	437634	00

43763401 Cotty, P. (1995) Aspergillus flavus Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 85 p.

	SBMTR	SBMSN	DATE	ADMIN-NR	ACCSN	SFX
01 OF 02	069224		08/09/95	069224-EX1	437634	01
02 OF 02	069224		08/09/95	5E4575-	437634	01

43763402 Cotty, P. (1995) Aspergillus flavus Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits, and Physical and Chemical Properties: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 8 p.

	SBMTR	SBMSN	DATE	ADMIN-NR	ACCSN	SFX
01 OF 02	069224		08/09/95	069224-EX1	437634	02
02 OF 02	069224		08/09/95	5E4575-	437634	02

43763403 Cotty, P.; Hartman, C. (1995) Aspergillus flavus Isolate AF36--Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirements of a Tolerance for Aspergillus flavus for Use in Cotton Production: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 882 p.

	SBMTR	SBMSN	DATE	ADMIN-NR	ACCSN	SFX
01 OF 02	069224		08/09/95	069224-EX1	437634	03
02 OF 02	069224		08/09/95	5E4575-	437634	03

43763404 Cotty, P. (1995) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents with Microbial Pest Control Agents: Statement of Finding No Hypersensitivity: Lab Project Number:

PR 52B. Unpublished study prepared by USDA/ARS. 4 p.

SBMTR	SBMSN	DATE	ADMIN-NR	ACCSN	SFX
01 OF 02	069224	08/09/95	069224-EX1	437634	04
02 OF 02	069224	08/09/95	5E4575-	437634	04

43763405 Cotty, P.; Hartman, C. (1995) Aspergillus flavus Isolate AF36: Product Performance Data: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 145 p.

SBMTR	SBMSN	DATE	ADMIN-NR	ACCSN	SFX
01 OF 02	069224	08/09/95	069224-EX1	437634	05
02 OF 02	069224	08/09/95	5E4575-	437634	05

43972400 Interregional Research Project No. 4 (1996) Submission of Product Analysis and Toxicology Data in Support of an Experimental Use Permit for Aspergillus flavus AF36. Transmittal of 3 Studies.

SBMTR	SBMSN-DATE	ADMIN-NR	ACCSN	SFX
01 OF 01	959857 04/03/96	069224-EX1	439724	00

43972401 Cotty, P. (1996) Aspergillus flavus Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits: Amendment No. 1 to MRID No. 43763404: Lab Project Number: PR 52B: 52B. Unpublished study prepared by Southern Regional Research Center, USDA/ARS. 6 p.

SBMTR	SBMSN-DATE	ADMIN-NR	ACCSN	SFX
01 OF 01	959857 04/03/96	069224-EX1	439724	01

43972402 Cotty, P. (1996) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents with Microbial Pest Control Agents: Statement of Finding of No Hypersensitivity: Amendment No. 1 to MRID No. 43763404: Lab Project Number: 52B: PR 52B. Unpublished study prepared by Southern Regional Research Center, USDA/ARS. 4 p.

SBMTR	SBMSN-DATE	ADMIN-NR	ACCSN	SFX
01 OF 01	959857 04/03/96	069224-EX1	439724	02

43972403 Shelton, L. (1996) Acute Oral Toxicity Study in Rats: (Aspergillus flavus AF36): Final Report: Lab Project Number: M96AG84.6G31: MA M96AG84.6G31. Unpublished study prepared by

Microbiological Associates, Inc. 59 p.

SBMTR	SBMSN-DATE	ADMIN-NR	ACCSN	SFX
01 OF 01	959857	04/03/96	069224-EX1	439724 03

43990000 Interregional Research Project No. 4 (1996) Submission of Product Chemistry Data in Support of the Application for Experimental Use Permit for Apergillus flavus AF36. Transmittal of 1 Study.

SBMTR	SBMSN-DATE	ADMIN-NR	ACCSN	SFX
01 OF 01	959857	04/24/96	069224-EX1	439900 00

43990001 Cotty, P. (1996) Aspergillus flavus Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process, and Discussion on the Formation of Unintentional Ingredients: Amendment No. 1 to MRID 43763401: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS, Southern Regional Research Center. 6 p.

SBMTR	SBMSN-DATE	ADMIN-NR	ACCSN	SFX
01 OF 01	959857	04/24/96	069224-EX1	439900 01

44597000 Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerance of Aspergillus flavus isolate AF36 in/on Wheat. Transmittal of 1 Study.

SBMTR	SBMSN-DATE	ADMIN-NR	ACCSN	SFX
01 OF 01	959857	07/01/98	8E5001-	445970 00

44597001 Cotty, P.; Antilla, L. (1998) Aspergillus flavus Isolate AF36 Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 MRID 43763401: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, Arizona Cotton Research and Protection Council and Rutgers Univ. 38 p.

SBMTR	SBMSN-DATE	ADMIN-NR	ACCSN	SFX
01 OF 01	959857	07/01/98	8E5001-	445970 01

44626100 Interregional Research Project No. 4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerance

of Aspergillus flavus isolate AF36 in/on Cotton. Transmittal of 1 Study.

	SBMTR	SBMSN	DATE	ADMIN-NR	ACCSN	SFX
01 OF 02	069224		08/06/98	069224-EX1	446261	00
02 OF 02	959857		08/06/98	5E4575-	446261	00

44626101 Cotty, P.; Antilla, L. (1998) Aspergillus flavus isolate AF36-Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits: Amendment No. 2 to MRID No. 43763402: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, and Arizona Cotton Research and Protection Council. 33 p.

	SBMTR	SBMSN	DATE	ADMIN-NR	ACCSN	SFX
01 OF 02	069224		08/06/98	069224-EX1	446261	01
02 OF 02	959857		08/06/98	5E4575-	446261	01

44713700 Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerances of Aspergillus flavus in/on Cotton. Transmittal of 1 Study.

	SBMTR	SBMSN	DATE	ADMIN-NR	ACCSN	SFX
01 OF 03	959857		12/11/98	8E5001-	447137	00
02 OF 03	959857		12/11/98	5E4575-	447137	00
03 OF 03	959857		12/11/98	069224-EX1	447137	00

44713701 Cotty, P.; Antilla, L. (1998) Aspergillus Flavus isolate AF36--Amended Manufacturing Process--Amendment No.3: Lab Project Number: 52B. Unpublished study prepared by IR-4. 21 p.

	SBMTR	SBMSN	DATE	ADMIN-NR	ACCSN	SFX
01 OF 03	959857		12/11/98	8E5001-	447137	01
02 OF 03	959857		12/11/98	5E4575-	447137	01
03 OF 03	959857		12/11/98	069224-EX1	447137	01

45307200 USDA/ARS Southern Regional Research Center (2001) Submission of Environmental Fate Data in Support of the Petition for Tolerance of Aspergillus flavus Isolate AF36/Cotton in/on Cotton. Transmittal of 2 Studies.

	SBMTR	SBMSN	DATE	ADMIN-NR	ACCSN	SFX
01 OF 02	069224		01/18/01	5E4575-	453072	00
02 OF 02	069224		01/18/01	069224-EX1	453072	00

45307201 Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus): Lab Project Number: 52B. Unpublished study prepared by Interregional Research Project No.4. 130 p.

	SBMTR	SBMSN	DATE	ADMIN-NR	ACCSN	SFX
01 OF 02	069224		01/18/01	5E4575-	453072	01
02 OF 02	069224		01/18/01	069224-EX1	453072	01

45307202 Cotty, P. (2001) Aspergillus flavus Isolate AF36 Non-target Organism and Environmental Safety Information (Soil and Air Monitoring of Populations of A. flavus): Lab Project Number: 52B. Unpublished study prepared by Interregional Research Project No.4. 130 p.

	SBMTR	SBMSN	DATE	ADMIN-NR	ACCSN	SFX
01 OF 02	069224		01/18/01	5E4575-	453072	02
02 OF 02	069224		01/18/01	069224-EX1	453072	02

Bib gdln 52002.wpd

151-10 Product Identity and Disclosure of Ingredients

MRID	Citation Reference
44626101	Cotty, P.; Antilla, L. (1998) Aspergillus flavus isolate AF36-Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits: Amendment No. 2 to MRID No. 43763402: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, and Arizona Cotton Research and Protection Council. 33 p.

151-11 Manufacturing Process

MRID	Citation Reference
44713701	Cotty, P.; Antilla, L. (1998) Aspergillus Flavus isolate AF36--Amended Manufacturing Process--Amendment No.3: Lab Project Number: 52B. Unpublished study prepared by IR-4. 21 p.

151-13 Analysis of Samples

MRID	Citation Reference
44626101	Cotty, P.; Antilla, L. (1998) Aspergillus flavus isolate AF36-Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits: Amendment No. 2 to MRID No. 43763402: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, and Arizona Cotton Research and Protection Council. 33 p.

151-15 Certification of Ingredient Limits

MRID	Citation Reference
44626101	Cotty, P.; Antilla, L. (1998) Aspergillus flavus isolate AF36-Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits: Amendment No. 2 to MRID No. 43763402: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, and Arizona Cotton Research and Protection Council. 33 p.

151-20 Product Identity and Disclosure of Ingredients

MRID	Citation Reference
43763401	Cotty, P. (1995) Aspergillus flavus Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 85 p.
43763402	Cotty, P. (1995) Aspergillus flavus Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits, and Physical and Chemical Properties: Lab Project Number: PR 52B. Unpublished

study prepared by USDA/ARS. 8 p.

43990001 Cotty, P. (1996) Aspergillus flavus Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process, and Discussion on the Formation of Unintentional Ingredients: Amendment No. 1 to MRID 43763401: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS, Southern Regional Research Center. 6 p.

44597001 Cotty, P.; Antilla, L. (1998) Aspergillus flavus Isolate AF36 Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 MRID 43763401: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, Arizona Cotton Research and Protection Council and Rutgers Univ. 38 p.

151-21 Manufacturing Process

MRID Citation Reference

43763401 Cotty, P. (1995) Aspergillus flavus Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 85 p.

43972401 Cotty, P. (1996) Aspergillus flavus Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits: Amendment No. 1 to MRID No. 43763404: Lab Project Number: PR 52B: 52B. Unpublished study prepared by Southern Regional Research Center, USDA/ARS. 6 p.

44597001 Cotty, P.; Antilla, L. (1998) Aspergillus flavus Isolate AF36 Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 MRID 43763401: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, Arizona Cotton Research and Protection Council and Rutgers Univ. 38 p.

151-22 Discussion of Formation of Unintentional Ingredients

MRID Citation Reference

43763401 Cotty, P. (1995) Aspergillus flavus Isolate AF36--Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 85 p.

44597001 Cotty, P.; Antilla, L. (1998) Aspergillus flavus Isolate AF36 Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 MRID 43763401: Lab Project Number: 52B. Unpublished

study prepared by USDA/ARS, Arizona Cotton Research and Protection Council and Rutgers Univ. 38 p.

151-25 Analytical Methods for Certified Limits

MRID	Citation Reference
43763402	Cotty, P. (1995) Aspergillus flavus Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits, and Physical and Chemical Properties: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 8 p.
44597001	Cotty, P.; Antilla, L. (1998) Aspergillus flavus Isolate AF36 Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 MRID 43763401: Lab Project Number: 52B. Unpublished study prepared by USDA/ARS, Arizona Cotton Research and Protection Council and Rutgers Univ. 38 p.

151-26 Physical and Chemical Properties

MRID	Citation Reference
43763402	Cotty, P. (1995) Aspergillus flavus Isolate AF36--Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits, and Physical and Chemical Properties: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 8 p.

152-30 Acute Oral Toxicity/infectivity

MRID	Citation Reference
43972403	Shelton, L. (1996) Acute Oral Toxicity Study in Rats: (Aspergillus flavus AF36): Final Report: Lab Project Number: M96AG84.6G31: MA M96AG84.6G31. Unpublished study prepared by Microbiological Associates, Inc. 59 p.

152-37 Hypersensitivity Incidents

MRID	Citation Reference
43763404	Cotty, P. (1995) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents with Microbial Pest Control Agents: Statement of Finding No Hypersensitivity: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS. 4 p.
43972402	Cotty, P. (1996) Aspergillus flavus Isolate AF36: Hypersensitivity Incidents with Microbial Pest Control Agents: Statement of Finding of No Hypersensitivity: Amendment No. 1 to MRID No. 43763404: Lab Project Number: 52B: PR 52B. Unpublished study prepared by Southern Regional Research Center, USDA/ARS. 4 p.

Non-Guideline Study

MRID	Citation Reference
43763400	USDA/ARS and IR-4 (1995) Submission of Product Chemistry, Toxicity, and Risk Data in Support of an Experimental Use Permit for Aspergillus flavus AF36. Transmittal of 5 Studies.
43763403	Cotty, P.; Hartman, C. (1995) Aspergillus flavus Isolate AF36--Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirements of a Tolerance for Aspergillus flavus for Use in Cotton Production: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 882 p.
43763405	Cotty, P.; Hartman, C. (1995) Aspergillus flavus Isolate AF36: Product Performance Data: Lab Project Number: PR 52B. Unpublished study prepared by USDA/ARS and IR-4. 145 p.
43972400	Interregional Research Project No. 4 (1996) Submission of Product Analysis and Toxicology Data in Support of an Experimental Use Permit for Aspergillus flavus AF36. Transmittal of 3 Studies.
43990000	Interregional Research Project No. 4 (1996) Submission of Product Chemistry Data in Support of the Application for Experimental Use Permit for Apergillus flavus AF36. Transmittal of 1 Study.
44597000	Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerance of Aspergillus flavus isolate AF36 in/on Wheat. Transmittal of 1 Study.
44626100	Interregional Research Project No. 4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerance of Aspergillus flavus isolate AF36 in/on Cotton. Transmittal of 1 Study.
44713700	Interregional Research Project No.4 (1998) Submission of Product Chemistry Data in Support of the Petition for Tolerances of Aspergillus flavus in/on Cotton. Transmittal of 1 Study.
45307200	USDA/ARS Southern Regional Research Center (2001) Submission of Environmental Fate Data in Support of the Petition for Tolerance of Aspergillus flavus Isolate AF36/Cotton in/on Cotton. Transmittal of 2 Studies.
45307201	Cotty, P. (2001) Aspergillus flavus Isolate AF36: Safety Information (Soil and Air Monitoring of Populations of A. flavus): Lab Project Number: 52B. Unpublished study prepared by Interregional Research Project No.4. 130 p.

45307202 Cotty, P. (2001) Aspergillus flavus Isolate AF36 Non-target Organism and Environmental Safety Information (Soil and Air Monitoring of Populations of A. flavus): Lab Project Number: 52B. Unpublished study prepared by Interregional Research Project No.4. 130 p.

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[Federal Register: July 17, 2002 (Volume 67, Number 137)]
[Rules and Regulations]
[Page 46884-46888]
>From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:frl7jy02-21]

ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 180
[OPP-2002-0093; FRL-7185-4]
RIN 2070

Aspergillus flavus AF36; Amendment, Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This regulation amends an existing temporary exemption from the requirement of a tolerance for residues of the atoxigenic microbial pesticide, Aspergillus flavus AF36 on cotton consistent with the Experimental Use Permit 69224-EUP-1, which will now allow for application to cotton in certain counties in Arizona and Texas. Interregional Research Project Number 4 (IR-4), on behalf of the USDA/ARS Southern Regional Research Center, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, requesting the temporary tolerance exemption amendment. This regulation eliminates the need to establish a maximum permissible level for residues of Aspergillus flavus AF36. The temporary tolerance exemption will expire on December 30, 2004.

DATES: This regulation is effective July 17, 2002. Objections and requests for hearings, identified by docket ID number OPP-2002-0093, must be received by EPA on or before September 16, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VIII. of the SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP-2002-0093 in the

subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shanaz Bacchus, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703-308-8097; e-mail address: <A HREF="mailto:bacchus.shanaz@epa.gov">bacchus.shanaz@epa.gov</A>.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. Electronically. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <A HREF="http://www.epa.gov/">http://www.epa.gov/</A>. To access this

[[Page 46885]]

document, on the Home Page select ``Laws and Regulations,'' ``Regulations and Proposed Rules,'' and then look up the entry for this document under the ``Federal Register--Environmental Documents.'' You can also go directly to the Federal Register listings at <A HREF="http://www.epa.gov/fedrgstr/">http://www.epa.gov/fedrgstr/</A>. A frequently updated electronic version of 40 CFR part 180 is available at <A HREF="http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html">http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html</A>, a beta site currently under development.

2. In person. The Agency has established an official docket for

this action under docket ID number OPP-2002-0093. The official docket consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). Interested parties should consult both the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official docket does not include any information claimed as CBI. The public version of the official docket, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Authority

A. Statutory Authority

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ``safe.'' Section 408(c)(2)(A)(ii) defines ``safe'' to mean that ``there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ``ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' Additionally, section 408(b)(2)(D) requires that the Agency consider ``available information concerning the cumulative effects of a particular pesticide's residues'' and ``other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

B. Factual Background

This extension of the temporary exemption from the requirement of a tolerance is associated with an extension of an Experimental Use Permit (69224-EUP-1), which was granted in May 1996 to the Southern Regional Research Center, United States Department of Agriculture, Agricultural Research Service (USDA ARS), 1100 Robert E. Lee Blvd., New Orleans, LA 70179-0687. Both the temporary exemption from tolerance and the Experimental Use Permit in Arizona expire December 30, 2003.

In the Federal Register of (March 25 2002, 57 FR 13628) (FRL-6827-8), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104-170), announcing the filing of an amended pesticide tolerance petition (PP 5E4575) by Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, Technology Center of New Jersey, 681 U.S. Highway <greek-i>1 South, North Brunswick, NJ 08902-3390 on behalf of the USDA/ ARS Southern Regional Research Center, 1100 Robert E. Lee Blvd., P.O. Box 19687, New Orleans, LA 70179. This notice included a summary of the petition prepared by the petitioner, Dr. Michael Braverman. It referred

to data previously evaluated and summarized by the Agency as published in the Federal Register of May 26 1999 (64 FR 28371) (FRL-6081-2), and the extension of the temporary tolerance exemption as published in the Federal Register of May 23 2001 (66 FR 28383) (FRL-6781-7). The petition requested that 40 CFR part 180.1206 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of Aspergillus flavus AF36 on cotton in certain counties in Texas in addition to the current exemption from temporary tolerance on cotton in Arizona. This petition also, requested that this temporary exemption from a tolerance be extended to December 30, 2005.

Several comments were received in favor of the amendment to allow use of the microbial pesticide in Texas. The growers were of the opinion that the use of this active ingredient is likely to reduce the high levels of naturally occurring aflatoxin-producing strain. Aspergillus flavus AF36 has been found at a range of less than 1 to approximately 5% in certain regions of Texas.

One comment was received requesting the Agency to re-evaluate the science of the proposed program and that the risks associated with the use of the active ingredient be considered before a permanent exemption from a tolerance is issued. The main concerns in this comment were the requirement for uniform standards in the expression of aflatoxin levels found in the crop; the practical significance of the proposed treatment method in reducing aflatoxin contamination; and the significance of the host stress in the expression of pathogenicity by Aspergillus flavus.

Considering each of these points, first, the commenter referred to the mixing of units used to measure aflatoxin contamination. This comment specifically referred to the experimental researcher's reports, which include measurement of aflatoxin levels as micrograms per gram of cottonseed rather than the typical expression of micrograms per kilogram of cottonseed. In data submitted to the Agency, there is no indication that the company was in error or misrepresenting the aflatoxin values. In all cases, EPA is careful to pay close scrutiny to the units of measure in data they review and the implications made from the stated values.

Secondly, the efficacy of the pesticidal product to reduce the level of aflatoxin in commercial crops was questioned in the comments. The Agency requires that the company present data to confirm their claim to control a public health hazard. The submitted data are available in the public docket and have been reviewed. These data indicate that when Aspergillus flavus AF36 is used, a higher percentage of the treated commodity meets, or is less than, the standards of aflatoxin required by the Food and Drug Administration (FDA), and the aflatoxin contamination in the experimental region is lowered. The growers ultimately decide if the reduced aflatoxin contamination is worth the treatment cost, but all cotton and its by-products sold for food/feed must meet the FDA aflatoxin standard.

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Regarding testing of the atoxigenic fungus, Aspergillus flavus AF36, on stressed or immunosuppressed species to detect any pathogenic potential in plants, insects, or mammals, EPA's guideline requirements are designed to address the normal immune response to microbial exposure. These tests include non-self/foreign recognition and response or clearance by the immune system over time. EPA is examining new methods that may address the potential of a microbe to infect stressed or immunocompromised hosts. In the interim, special measures have been included in the experimental treatments to reduce exposure to Aspergillus flavus AF36 outside of the designated treatment areas. The experimental plan also requires extensive data collection to examine the fate and persistence of Aspergillus flavus AF36 as a component of

the local fungal population.

Exposure to Aspergillus flavus is inevitable, because the fungus normally occurs in the environment. Given the ubiquitous nature of various strains of Aspergillus flavus, the precautions associated with this experimental program, data indicating no undue adverse health effects to test rodent species by oral ingestion of Aspergillus flavus AF36, as well as the current FDA monitoring of aflatoxin levels, there is a reasonable certainty of no harm resulting from the use of the non-aflatoxin-producing fungus, Aspergillus flavus AF36.

III. Toxicological Profile and Risk Assessment

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Based on the data and analyses outlined in the Federal Register of May 26 1999 (66 FR 28371), and summarized below, EPA has concluded that there is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to residues of Aspergillus flavus AF36 arising from the limited use pattern of the experimental use permit. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

1. Food. The cultural practice allows application of the microbial pesticide prebloom to cotton. This precludes the potential for direct residues of Aspergillus flavus AF36 per se to remain on the treated cotton. Only the seed of the treated commodity, cotton, is likely to be processed as food for cottonseed oil. Residues of Aspergillus flavus AF36 or its metabolites are likely to be removed from cotton seed oil during this processing.

In addition, the data submitted demonstrate that the proposed strain of Aspergillus flavus AF36, has a low toxicity potential, and, therefore, is likely to pose a minimal to non-existent hazard if used as labeled. The acute oral LD₅₀ of rats treated by gavage for 14 days is greater than 5,000 mg/kg. Further, the proposed strain of Aspergillus flavus, AF36, does not produce aflatoxin. Aflatoxin is regulated on the by-products of cotton by the Food and Drug Administration. The May 23 2001 Federal Register Notice also, discusses that no adverse effects were reported in the annual reports of the Experimental Use Permit 69224-EUP-1, and, in some instances, aflatoxin levels of cotton seed were reduced in treated cotton (May 23, 2001, 66 FR 28383).

2. Dermal exposure. Non-occupational dermal exposure and risk to adults, infants and children are not likely if the pesticide is used as labeled. If the microbe exhibits dermal sensitizing properties which is associated with this genus of fungi, the boundaries are likely to maintain distribution near treated areas thus protecting nearby at-risk populations. To further minimize exposure to immunocompromised or sensitive populations, infants and children, the Agency continues to require that the pesticide must not be applied within a boundary of 400 feet of schools, daycare and health care facilities and hospitals.

3. Inhalation exposure. Based on the method of application to the soil of cultivated cotton fields, prebloom with set boundaries, non-occupational inhalation exposure and risk to human adults, children and infants are likely to be minimal.

4. Determination of safety for U.S. population, infants and children. FFDCA section 408 provides that EPA shall apply an additional

tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. In this instance, based on the above findings, EPA believes there are reliable data to support the conclusion that there are no threshold effects of concern to infants, children, and adults when Aspergillus flavus AF36 is used as labeled, and that no additional margin of exposure is necessary.

5. Cumulative effects. This is the only microbe in the genus Aspergillus which is in an experimental use program at this time. Aspergillus species are naturally occurring ubiquitous fungi, such that exposure to various species is normal. The data submitted to the Agency support the claim that Aspergillus flavus AF36 is non-aflatoxin producing. When applied prior to flowering, Aspergillus flavus has been shown to exclude aflatoxin-producing fungi competitively from the developing crop and to reduce aflatoxin contamination of cottonseed. Data show that the proposed use will not result in appreciable increases in the long-term populaton of Aspergillus flavus on the crop beyond naturally occurring levels. Furthermore, there is no expectation of cumulative effects with other pesticides.

IV. Other considerations

1. Endocrine disruptors. EPA does not have any information regarding endocrine effects of this microbial pesticide at this time.

2. Analytical methods. Starter cultures are screened on the basis of vegetative incompatibility with the toxigenic strain. Aspergillus flavus AF 36 does not demonstrate vegetative compatibility with the aflatoxin-producing S strain. Aflatoxin production is monitored by standard thin layer chromatography (tlc) procedures and visualization via scanning fluorescence densitometry and there is a zero tolerance for aflatoxin. Human pathogens are reported to be within regulatory levels (May 26 1999, 64 FR 28371). Treated cotton and its by-products are screened for aflatoxin prior to introduction into the channels of commerce. FDA does not allow cotton seed products containing aflatoxin above 20 parts per billion (ppb) to be used in dairy rations or above 300 ppb to be used for feeding beef cattle.

3. Codex maximum residue level. There is no codex maximum residue level for Aspergillus flavus AF36.

V. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the

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FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ``object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2002-0093 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 16, 2002.

1. Filing the request. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. Tolerance fee payment. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ``Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ``when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at <A HREF="mailto:tompkins.jim@epa.gov">tompkins.jim@epa.gov</A>, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. Copies for the docket. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP-2002-0093, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: <A HREF="mailto:opp-docket@epa.gov">opp-docket@epa.gov</A>. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will

also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VI. Regulatory Assessment Requirements

This final rule establishes an amended exemption from the temporary tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (October 4 1993, 58 FR 51735). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (May 22 2001, 66 FR 28355). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (February 16 1994, 59 FR 7629); or OMB review or any Agency action under Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (April 23 1997, 62 FR 19885). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the amended temporary tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601et seq.) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various

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levels of government, as specified in Executive Order 13132, entitled Federalism (August 10 1999, 64 FR 43255). Executive Order 13132 requires EPA to develop an accountable process to ensure ``meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ``Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ``substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates

growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ``tribal implications'' as described in Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (November 6, 2000, 65 FR 67249). Executive Order 13175, requires EPA to develop an accountable process to ensure ``meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ``Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ``substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the Federal Register. This final rule is not a ``major rule ''as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 27, 2002.
Janet L. Andersen,
Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 374.

2. Section 180.1206 is revised to read as follows:

Sec. 180.1206 Aspergillus flavus AF36.

Aspergillus flavus AF36 is temporarily exempt from the requirement of a tolerance in or on cotton. The temporary exemption from a tolerance will expire on December 30, 2004, consistent with the Experimental Use Permit 69224-EUP-1.

[FR Doc. 02-17869 Filed 7-16-02; 8:45 am]
BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0093; FRL–7185–4]

RIN 2070

Aspergillus flavus AF36; Amendment, Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends an existing temporary exemption from the requirement of a tolerance for residues of the atoxigenic microbial pesticide, *Aspergillus flavus* AF36 on cotton consistent with the Experimental Use Permit 69224–EUP–1, which will now allow for application to cotton in certain counties in Arizona and Texas. Interregional Research Project Number 4 (IR-4), on behalf of the USDA/ARS Southern Regional Research Center, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, requesting the temporary/tolerance exemption amendment. This regulation eliminates the need to establish a maximum permissible level for residues of *Aspergillus flavus* AF36. The temporary tolerance exemption will expire on December 30, 2004.

DATES: This regulation is effective [*insert date of publication in the* Federal Register]. Objections and requests for hearings, identified by docket ID number OPP–2002–0093, must be received by EPA on or before [*insert date 60 days after date of publication in the* Federal Register.]

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0093 in the subject line on the first page of your response.

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Right Of Rejection We reserve the right to reject a shipment when such shipment would be likely to cause delay or damage to other shipments, equipment, or personnel or if its shipment is prohibited by law; or if the shipment would violate any terms of our Agreement or our current Service Guide.

C.O.D. Services C.O.D. SERVICE IS NOT AVAILABLE WITH THIS AIRBILL. If C.O.D. Service is required, please use a Federal Express C.O.D. airbill.

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- FedEx Express Saver Freight: Up to 3 business-day service to all points in the 48 states; rates are based upon the distance shipped.

Interregional Research Project No. 4
Center for Minor Crop Pest Management

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division
Environmental Protection Agency
Room 910, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia

June 7, 2002

RE: Aspergillis flavus AF36 PC Code 006456
Minutes of meeting- Section 3 Registration May 30, 2002

EPA Participants- Janet Andersen, Phil Hutton, Shanaz Bacchus, Gail Tomimatsu, Zigfridass Vaituzis, Carl Etsitty

Registrant Related Participants- Peter Cotty-USDA/ARS, Phil Wakelyn, Keith Menchey-National Cotton Council, Larry Antilla- Arizona Cotton Research and Protection Council, Chuck Youngker, Arizona Cotton Growers Association, Michael Braverman-IR-4 Project.

Dear Janet:

On behalf of the USDA/ARS, National Cotton Council, Arizona Cotton Council, Arizona Cotton Growers Association and the IR-4 Project, I would like to thank you and your staff for taking the time to meet with us to discuss the section 3 registration of *Aspergillis flavus* AF-36 on May 30, 2002. We were especially impressed with your interest and questions about the project and its importance to growers and public health. According to my records, the last Section 3 meeting was held about two years ago on June 27, 2000 (copy attached). It appears that from that previous meeting it was agreed that the studies needed to complete the registration package were the toxicology studies, which have now been completed.

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

The most important highlights of the current meeting and our understanding of what is needed to complete the data requirements for Section 3 registration for AF-36 and the timetable for EPA review of these data are as follows:

When formally submitted (and assuming they are acceptable), the mammalian, avian and bee toxicology studies will essentially complete the data requirements for the section 3 registration.

Many parts of the current label language were developed due to the lack of toxicology data and if justified, can be modified.

The goal for section 3 registration is February 2003 so that we can avoid the inefficiency of having to request and review an additional expansion of the EUP.

The following are our minutes from the current meeting.

Phil Wakelyn made some opening comments about the importance of this project to cotton growers and that this was a grassroots effort, made up of direct interactions among growers, gins and public agencies. The product is manufactured by the Arizona Cotton Research and Protection Council (a component of the Arizona Department of Agriculture) and distributed directly to growers. He also highlighted the fact that there are no chemical alternatives to aflatoxin management and the agricultural industry welcomed an effective biopesticide solution. EPA appreciated the innovative approach and direct grower involvement.

Larry Antilla talked about the building of the production facility in Arizona over the last 3 years and that about 46,000 acres had been treated. Case studies of aflatoxin reduction figures on several farms were reviewed. One farm with approximately 1,000 acres of cotton had previously never been able to produce cottonseed below 20 ppb. In 2000, that farm produced seed with acceptable aflatoxin contents (<20 ppb) on 82% of its 17 treated fields and in 2001, 86% of treated fields produced cottonseed with acceptable aflatoxin contents. Chuck Younger gave a personal perspective on the aflatoxin problem in Arizona and noted that growers have committed $2.4 million dollars to the research program. In addition, it was pointed out that the only means of mitigation for high aflatoxin levels in seed involves the injection of anhydrous ammonia, which is caustic and poses human health risks.

There was a general discussion of the toxicology data (which was unofficially submitted in early May). It was generally agreed that the Tween 80 used in the first mammalian study was responsible for some effects that were not related to AF36 which was confirmed by the second study. The toxicology data constitutes the remaining portion of the registration package to be submitted and must be officially submitted before being considered.

Many parts of the current label language were developed due to the lack of toxicology data and if justified, can be modified. The combination of acceptable toxicology data , the lack of an increase in total Aspergillus and a reduction in aflatoxin producing spores all contribute to a favorable risk profile due to no change in exposure combined with reduced hazard of AF-36 the spores to the environment. Some of the more specific parts to be considered included adding a

statement that AF36 can be applied to irrigated fields, removal of the buffer statement, wind direction statement, modification of the 12 month storage statement, statement related to inducing vomiting, and perhaps some others.

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Now it is up to us to get all of the data in for review so that our goal of section 3 registration by February 2003 can be achieved. While we were previously unaware that this was classified as a public health issue we assume that should add weight to the benefits consideration and prioritize its importance in the review process.

Sincerely,

Michael Braverman

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu

cc: Phil Hutton, Shanaz Bacchus, Gail Tomimatsu, Zigfridass Vaituzis, Carl Etsitty, John Kough
Peter Cotty, Phil Wakelyn, Keith Menchey, Larry Antilla, Chuck Youngker, Bob Holm

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

AUG 14 2002

Dr. Michael Braverman, Coordinator
Interregional Research Project No.4
681 US Highway #1 South
North New Brunswick, NJ 08902

Subject: Minutes of Meeting - Section 3 Registration: *Aspergillus flavus* AF36

Dear Dr. Braverman:

This letter responds to your letter of June 7, 2002 regarding the minutes of the meeting held here in Crystal City, May 30, 2002, to discuss the proposed Section 3 registration of *Aspergillus flavus* AF36.

The studies needed to complete the package are the mammalian toxicology studies to demonstrate the pulmonary effects of the active ingredient and the non-target avian pulmonary and honey bee study. Requests to waive data for other non-target organism or any other studies to fulfil ecological effects or other guideline requirements must be submitted in writing and be accompanied by sound scientific rationales.

When setting your goals for the Section 3 registration, please keep in mind that the approval depends on the timely submission of data as well as the acceptability of the submissions. If data reviews identify deficiencies, then supplementary data may be required to address those deficiencies. Such situations must be factored into your time line.

With regards to the label, you must consider the Agency's label requirements as outlined in the label review manual and the 40 CFR and modify the label accordingly.

You mention that you were not aware of aflatoxin reduction being a public health issue. In the Federal Register notice of February 14, 1996, (FR vol. 61, p. 5771) the Agency published the Notice of Receipt of the application for the Experimental Use Permit as

being of regional and national significance. Again on June 14, 1996, the discussion of the granting of the Experimental Use Permit (FR vol. 61 p. 30235) stated that the use of the microbial pesticide is intended to "protect public health". Efficacy data are required for all pesticides to mitigate public health hazards.

I trust that the foregoing clarifies the minutes of the meeting. If you have any additional questions regarding this registration, do not hesitate to email Shanaz Bacchus at bacchus.shanaz@epa.gov or call her on 703-308-8097.

Sincerely,

Willie H. Nelson

for Phil Hutton, Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division

ROUTING AND TRANSMITTAL SLIP

Date 7/30/02

TO: (Name, office symbol, room number, building, Agency/ Post)	Initials	Date
1. Carl Elsitty	[illegible]	8-06
2. Gail Tomamatsu	[illegible]	8-06
3. Zig Vaituzis	[illegible]	8/8/02
4. Phil Hutton (for Phil)	[illegible]	8/12/02
5. Janet Andersen		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate	X	Signature
	Coordination		Justify		

REMARKS

Response to Mins of meeting
A. Glavus AF 36

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/ Post)	Room No. — Bldg.
[signature]	CM2-9th
	Phone No. 308-8097

NSN 7540-00-935-5862
5041-103

OPTIONAL FORM 41 (Rev. 1-94)
Prescribed by GSA
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United States Environmental Protection Agency

AUG 14 2002

Dr. Michael Braverman, Coordinator
Interregional Research Project No.4
681 US Highway #1 South
North New Brunswick, NJ 08902

Subject: Minutes of Meeting - Section 3 Registration: *Aspergillus flavus* AF36

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CONCURRENCES

SYMBOL ►	7511C							
SURNAME ►	EBITT	TOMIMATSU	VAITUZIS					
DATE ►	Aug 6, '02	Aug 6 2002	Aug 8, 02					

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

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Sincerely,

Phil Hutton, Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division

Interregional Research Project No. 4
Center for Minor Crop Pest Management

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division
Environmental Protection Agency
Room 910, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia

June 7, 2002

RE: Aspergillis flavus AF36 PC Code 006456
Minutes of meeting- Section 3 Registration May 30, 2002

EPA Participants- Janet Andersen, Phil Hutton, Shanaz Bacchus, Gail Tomimatsu, Zigfridass Vaituzis, Carl Etsitty

Registrant Related Participants- Peter Cotty-USDA/ARS, Phil Wakelyn, Keith Menchey-National Cotton Council, Larry Antilla- Arizona Cotton Research and Protection Council, Chuck Youngker, Arizona Cotton Growers Association, Michael Braverman-IR-4 Project.

Dear Janet:

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Mammalian + nontarget avian + honeybee

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY

* For fulfillment of Federal Effects, [illegible] submission of all species toxicity testing or a formal request or waiver for further testing must be submitted. All waiver requests must be accompanied by scientific rationale. Several data reviews (please refer to table) have addressed the requirement of formal waiver requests. GT

The most important highlights of the current meeting and our understanding of what is needed to complete the data requirements for Section 3 registration for AF-36 and the timetable for EPA review of these data are as follows:

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* [illegible] acceptable [illegible]

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[illegible] Vol 61, p.5771 (2/14/96) that EUP is of regional/national significance.

Sincerely,

Michael Braverman

Vol 61, p30235 (6/14/96) – will protect public health

Michael Braverman, Ph.D
Biopesticide Coordinator
IR-4 Project, Rutgers University
Technology Centre of New Jersey
681 U.S. Highway 1 South
North Brunswick, New Jersey 08902-3390
Tel (732)932-9575 ext 610
FAX (732)932-8481
braverman@aesop.rutgers.edu

* I believe [illegible] GT agrees – this involves [illegible] specifically "tailored" [illegible]

cc: Phil Hutton, Shanaz Bacchus, Gail Tomimatsu, Zigfridass Vaituzis, Carl Etsitty, John Kough
Peter Cotty, Phil Wakelyn, Keith Menchey, Larry Antilla, Chuck Youngker, Bob Holm

Interregional Research Project No. 4
Center for Minor Crop Pest Management

Ms. Shanaz Bacchus and Mr. Phil Hutton
US EPA
BPPD/OPP (7511C)
Crystal Mall No. 2 (Room 902)
1921 Jefferson Highway
Arlington, VA 22202

JUL 11 2000

Subject: Pre-registration meeting on Aspergillus flavus AF36 on Cotton in Arizona

Dear Ms. Bacchus and Mr. Hutton:

Thank you for arranging the meeting at EPA on June 27, 2000. We found the meeting informative and productive. This letter is to confirm our understanding of the meeting between the US EPA, the Arizona Cotton Research and Protection Council, the National Cotton Council, Arizona Cotton Growers, IR-4 and Dr. Peter Cotty of the USDA/ARS. The following people were present.

US EPA

Michael Watson	OPP/BPPD
Doug Gurian-Sherman	OPP/BPPD
Zig Vaituzis	OPP/BPPD
Phil Hutton	OPP/BPPD
Shanaz Bacchus	OPP/BPPD
John Kough	OPP/BPPD

IR-4

Bill Biehn	Coordinator

continued .....

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

Arizona Cotton Research and Protection Council
Larry Antilla Staff Director

Arizona Cotton Growers Association
Chuck Youngker President

USDA/ARS
Peter Cotty Research Plant Pathologist

National Cotton Council
Phillip J. Wakelyn Senior Scientist

The purpose of this meeting was to discuss additional registration requirements needed for a full Section 3 registration for atoxigenic Aspergillus flavus AF 36 for use on cotton in Arizona and the results of Dr. Cotty's research on the airborne spore levels of flavus in treated and untreated fields. Dr. Cotty also presented additional information regarding the widespread occurrence of A. flavus in the natural desert habitats in Arizona as well as other results.

Points Made During Meeting

- Peaks in airborne spore counts of A. flavus occur from September to November. The number of airborne spores of A. flavus in cotton fields treated with A. flavus strain AF36 are not significantly different from the number of airborne spores of A. flavus in untreated fields.

- Acute Pulmonary Toxicity/Pathogenicity Requirement in Mammals.
This study should be conducted utilizing spores of A. flavus AF36. The dose should be based on 100 times the maximum exposure level possible (i.e. 450 cfu/m^3 x 100 equals 4.5 x 10^4 cfu/animal).

- Avian Acute Pulmonary Toxicity/Pathogenicity Requirement in Bobwhite Quail.
For AF36, the preferred method of administration is via aerosol inhalation. IR-4 will have EPA review the protocol before initiation of this study.

- Honey Bee Testing Requirement - EPA will provide IR-4 with sample protocols and EPA will review the protocol prepared for AF36 before initiation of this study. A field exposure study would be adequate.

- Avian Acute Oral Toxicity/Pathogenicity Requirement. EPA indicated that this test could be waived. A request for a waiver of this study will be submitted to EPA. Since the avian acute pulmonary toxicity pathogenicity study will be done and since there is an "oral component" to the avian inhalation study, the pulmonary study should be sufficient. Additional scientific rationale will be provided with the formal submission of a waiver request for this study.

continued . . . . . .

- An application for an expanded and extended Experimental Use Permit (EUP) involving 80,000 to 95,000 acres as well as a request for an extension of the temporary tolerance exemption will be submitted to EPA in the near future.

Again, we want to thank you for the meeting. Please inform us of any suggested changes or additions to the minutes of this meeting. If we don't hear from you in 30 days, we will assume EPA is in agreement with the above minutes of the meeting.

Sincerely,

William L. Biehn

William L. Biehn, Ph.D.
Coordinator
IR-4 Project

WLB:js

cc: C. Youngker
L. Antilla
P. Cotty
P. Wakelyn
R. Holm
J. Baron

shared\judy\bill\bacchusm.wpd

Interregional Research Project No. 4
Center for Minor Crop Pest Management

Shanaz Bacchus
U.S. EPA
BPPD/OPP (7511C)
Crystal Mall No. 2, Room 902
1921 Jefferson Davis Highway
Arlington, VA 22202

MAR 15 2001

RE: *Aspergillus flavus* AF36/Cotton (AZ Only)

Dear Shanaz:

Attached is a table which provides further evidence that a 40,000 acre Experimental Use Permit (EUP) for *Aspergillus flavus* isolate AF36 will not result in a significant exposure of birds, animals and man to *Aspergillus flavus* in the six counties participating in the EUP program. The attached table shows that only 0.13% of the land area in the six Arizona counties participating in the EUP program (i.e. Maricopa, Pinal, Yuma, LaPaz, Mohave, and Pima) will be treated with *Aspergillus flavus* isolate AF36. In the three counties where 35,000 of the 40,000 acres are proposed for treatment with *Aspergillus flavus* isolate AF36, there are 737,285 acres of agricultural crops of which over 150,000 acres are in small grains. Up to 300 lbs. Of wheat and barley seed per acre are commonly left in the field during the small grains harvesting operation, much of which is contaminated with *A. flavus*. It has been previously shown that applications of *A. flavus* isolate AF36 will not increase the indigenous populations of *A. flavus* associated with the harvested crop and will not increase the number of airborne spores of *A. flavus* in or above cotton fields.

Sincerely,

William L. Biehn

William L. Biehn, Ph.D.
Coordinator
IR-4 Project

WLB:jb
Enclosure
cc: Larry Antilla/ACRPA Phil Hutton/EPA
Peter Cotty/USDA-ARS

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

Arizona counties in the Proposed 2001 EUP - Program with Aspergillus flavus AF36

a) Maximum acres of cotton to be treated in each county with AF36
b) % of total land area in each county to be treated with AF36
c) % of total planted acres in each county to be treated with AF36

#1 County	#2 Total Area (acres)	#3 Total Planted Acres (All Crops)	#4 Cotton Acres to be treated with AF36 [a]	#5 % of Total Area to be Treated with AF36[b]	#6 % of Total Planted Acres to be Treated with AF36[c]
Maricopa	5,916,000	291,770	15,000	0.25%	5.1%
Pinal	3,440,000	212,305	5,400	0.15%	2.5%
Yuma	3,527,000	233,210	6,000	0.17%	2.6%
LaPaz	2,887,000	88,900	7,000	0.24%	7.9%
Mohave	8,622,000	12,700	4,000	0.05%	31.5%
Pima	5,887,760	17,624	2,600	0.04%	14.8%
Total	30,275,760	856,509	40,000	0.13%	4.7%

[a] Approximate acres (figures are estimates and may vary ±10% by county)

[b] % of total area to be treated with AF36 = $\frac{\text{column \#4}}{\text{column \#2}}$

[c] % of total planted acres to be treated with AF36 = $\frac{\text{column \#4}}{\text{column \#3}}$

Interregional Research Project No. 4
Center for Minor Crop Pest Management

Shanaz Bacchus
U.S. EPA
BPPD/OPP (7511C)
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William L. Biehn, Ph.D.
Coordinator
IR-4 Project

WLB:jb
Enclosure
cc: Larry Antilla/ACRPA Phil Hutton/EPA
Peter Cotty/USDA-ARS

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

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a) Maximum acres of cotton to be treated in each county with AF36
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Total	30,275,760	856,509	40,000	0.13%	4.7%

[a] Approximate acres (figures are estimates and may vary ±10% by county)

[b] % of total area to be treated with AF36 = $\frac{\text{column \#4}}{\text{column \#2}}$

[c] % of total planted acres to be treated with AF36 = $\frac{\text{column \#4}}{\text{column \#3}}$

Interregional Research Project No. 4
Center for Minor Crop Pest Management

Shanaz Bacchus
U.S. EPA
BPPD/OPP (7511C)
Crystal Mall No. 2, Room 902
1921 Jefferson Davis Highway
Arlington, VA 22202

MAR 15 2001

RE: *Aspergillus flavus* AF36/Cotton (AZ Only)

Dear Shanaz:

Attached is a table which provides further evidence that a 40,000 acre Experimental Use Permit (EUP) for *Aspergillus flavus* isolate AF36 will not result in a significant exposure of birds, animals and man to *Aspergillus flavus* in the six counties participating in the EUP program. The attached table shows that only 0.13% of the land area in the six Arizona counties participating in the EUP program (i.e. Maricopa, Pinal, Yuma, LaPaz, Mohave, and Pima) will be treated with *Aspergillus flavus* isolate AF36. In the three counties where 35,000 of the 40,000 acres are proposed for treatment with *Aspergillus flavus* isolate AF36, there are 737,285 acres of agricultural crops of which over 150,000 acres are in small grains. Up to 300 lbs. Of wheat and barley seed per acre are commonly left in the field during the small grains harvesting operation, much of which is contaminated with *A. flavus*. It has been previously shown that applications of *A. flavus* isolate AF36 will not increase the indigenous populations of *A. flavus* associated with the harvested crop and will not increase the number of airborne spores of *A. flavus* in or above cotton fields.

Sincerely,

William L. Biehn

William L. Biehn, Ph.D.
Coordinator
IR-4 Project

WLB:jb
Enclosure
cc: Larry Antilla/ACRPA Phil Hulton/EPA
Peter Cotty/USDA-ARS Technology Centre of New Jersey

681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

Arizona counties in the Proposed 2001 EUP - Program with Aspergillus flavus AF36

a) Maximum acres of cotton to be treated in each county with AF36
b) % of total land area in each county to be treated with AF36
c) % of total planted acres in each county to be treated with AF36

#1 County	#2 Total Area (acres)	#3 Total Planted Acres (All Crops)	#4 Cotton Acres to be treated with AF36 [a]	#5 % of Total Area to be Treated with AF36[b]	#6 % of Total Planted Acres to be Treated with AF36[c]
Maricopa	5,916,000	291,770	15,000	0.25%	5.1%
Pinal	3,440,000	212,305	5,400	0.15%	2.5%
Yuma	3,527,000	233,210	6,000	0.17%	2.6%
LaPaz	2,887,000	88,900	7,000	0.24%	7.9%
Mohave	8,622,000	12,700	4,000	0.05%	31.5%
Pima	5,887,760	17,624	2,600	0.04%	14.8%
Total	30,275,760	856,509	40,000	0.13%	4.7%

[a] Approximate acres (figures are estimates and may vary ±10% by county)

[b] % of total area to be treated with AF36 = $\frac{\text{column \#4}}{\text{column \#2}}$

[c] % of total planted acres to be treated with AF36 = $\frac{\text{column \#4}}{\text{column \#3}}$

Interregional Research Project No. 4
Center for Minor Crop Pest Management

April 10, 2001

TO: Ms. Shanaz Bacchus

FROM: William L. Biehn Bill Biehn

SUBJECT: *Aspergillus flavus* AF36 for Use on Cotton in Arizona
AF36 Program Area Maps for Areas Proposed for Treatment in 2001

Attached are maps of the areas that will be treated in 2001. The areas that will be treated in 2001 are the Mohawk Valley in Yuma County; the Welton area in Yuma County; the Paloma area in Maricopa County; the Laveen area in Maricopa County; the Buckeye area in Maricopa County; the Maricopa Stanfield area in Pinal County; and the Mohave Valley in Mohave County.

We will adhere to a 400-foot buffer zone for all AF36 treatments with respect to certain facilities as per attached letter from Larry Antilla to Phil Hutton dated April 21, 1999.

WLB:el
Enclosure
cc: Peter Cotty, USDA-ARS
Larry Antilla, ACRPC

P.S. See Table 1 attached for acreage to be treated in each area.

Wpdoc/letters/bacchus

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

Table 1. Arizona Counties Proposed in the
2001 EUP-Program with *Aspergillus flavus* AF36

County	Areas to be Treated	Acres per Area [a/]	Total Acres per County [a/]
Maricopa	Laveen	6,150	
	Buckeye	600	
	Paloma	6,400	13,150
Pinal	Maricopa Stanfield	1,850	1,850
Yuma	Welton	1,400	
	Mohawk Valley	1,900	3,300
Mohave	Mohave Valley	1,700	1,700
		Total	20,000

[a/] Figures are estimates and may very by ±10% by county. Total acreage will not exceed 20,000 acres.

ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
2403 West Huntington, Suite 101,
Tempe, Arizona 85282-3166
(602) 438-0059
(602) 438-0407 - Fax

April 21, 1999

To : Phil Hutton
Environmental Protection Agency

From : Larry Antilla
Arizona Cotton Research and Protection Council

Subject: Buffer Zones

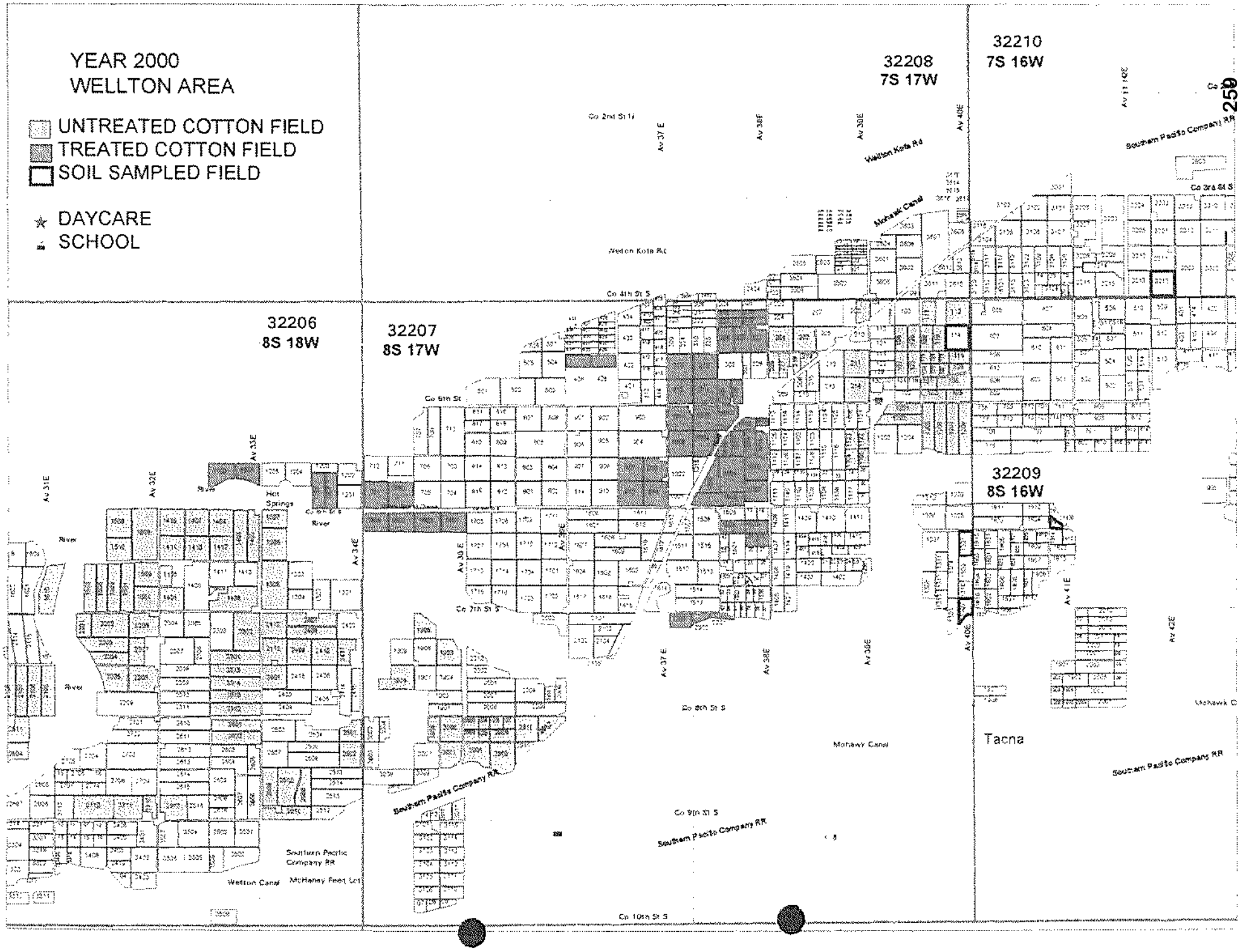
As per today's teleconference relative to Arizona's AF36 Aflatoxin reduction program, we agree to include the following in the operational protocol for Expanded EUP activities on cotton in Arizona in 1999.

> Establish and adhere to a 400 foot buffer zone for all AF36 treatments with respect to all hospitals, nursing homes, health care and other treatment centers where immune compromised individuals may be found. We will also include all schools and licensed day care centers in the protocol.

If you need additional clarification on the subject please contact me.

Thank you for your consideration of this matter.

AF36\PHutton lt


YEAR 2000
WELLTON AREA
UNTREATED COTTON FIELD
TREATED COTTON FIELD
SOIL SAMPLED FIELD
DAYCARE
SCHOOL
32206
8S 18W
32207
8S 17W
32208
7S 17W
32210
7S 16W
32209
8S 16W
Tacna
Hot Springs
River
Wellton Canal
McHaney Feed Lot
Southern Pacific Company RR
Mohawk Canal
Wellton Kofa Rd
Co 2nd St N
Co 3rd St S
Co 4th St S
Co 5th St
Co 6th St S
Co 7th St S
Co 8th St S
Co 9th St S
Co 10th St S
Av 31E
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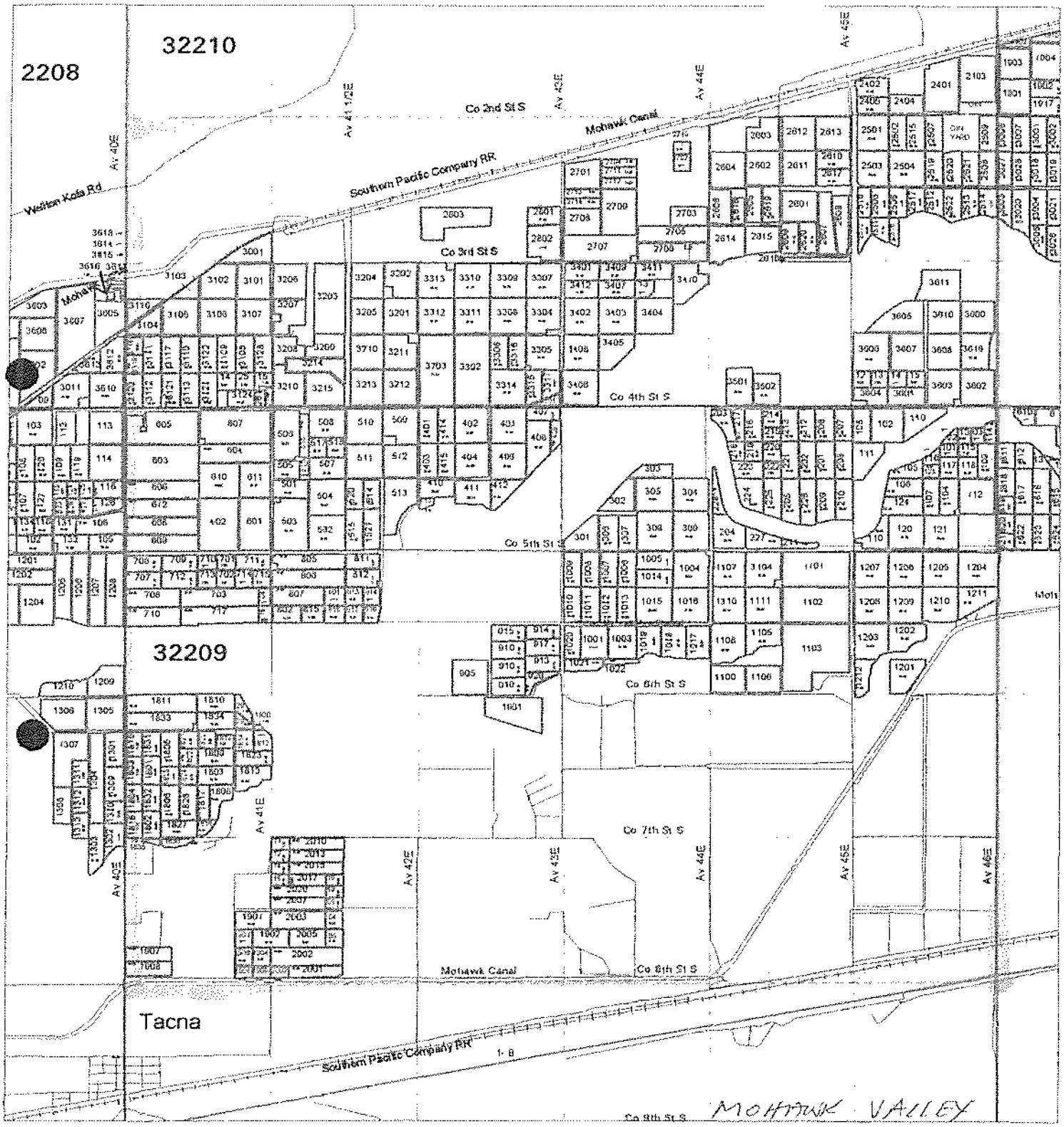
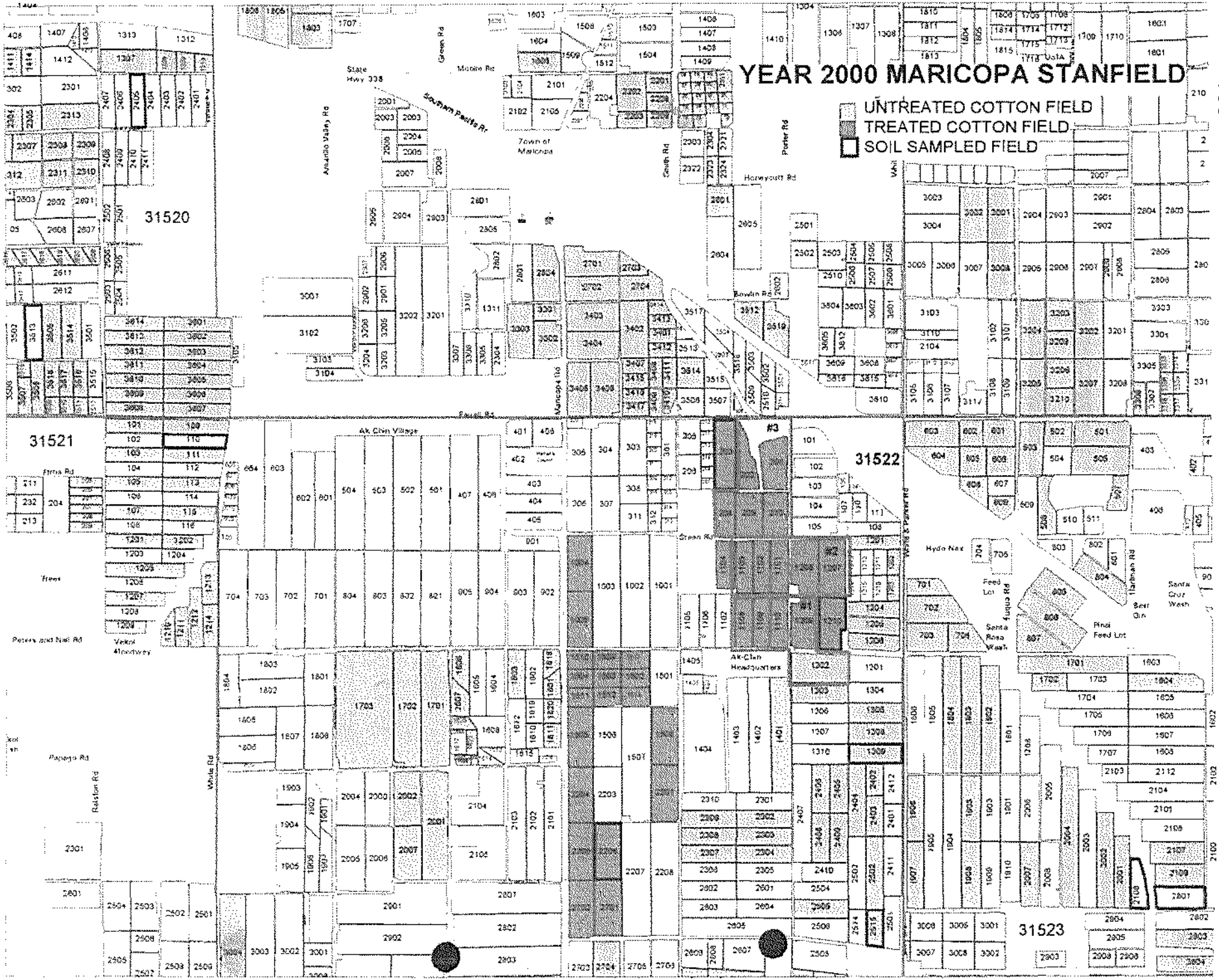
Av 38E
Av 39E
Av 40E
Av 41E
Av 42E

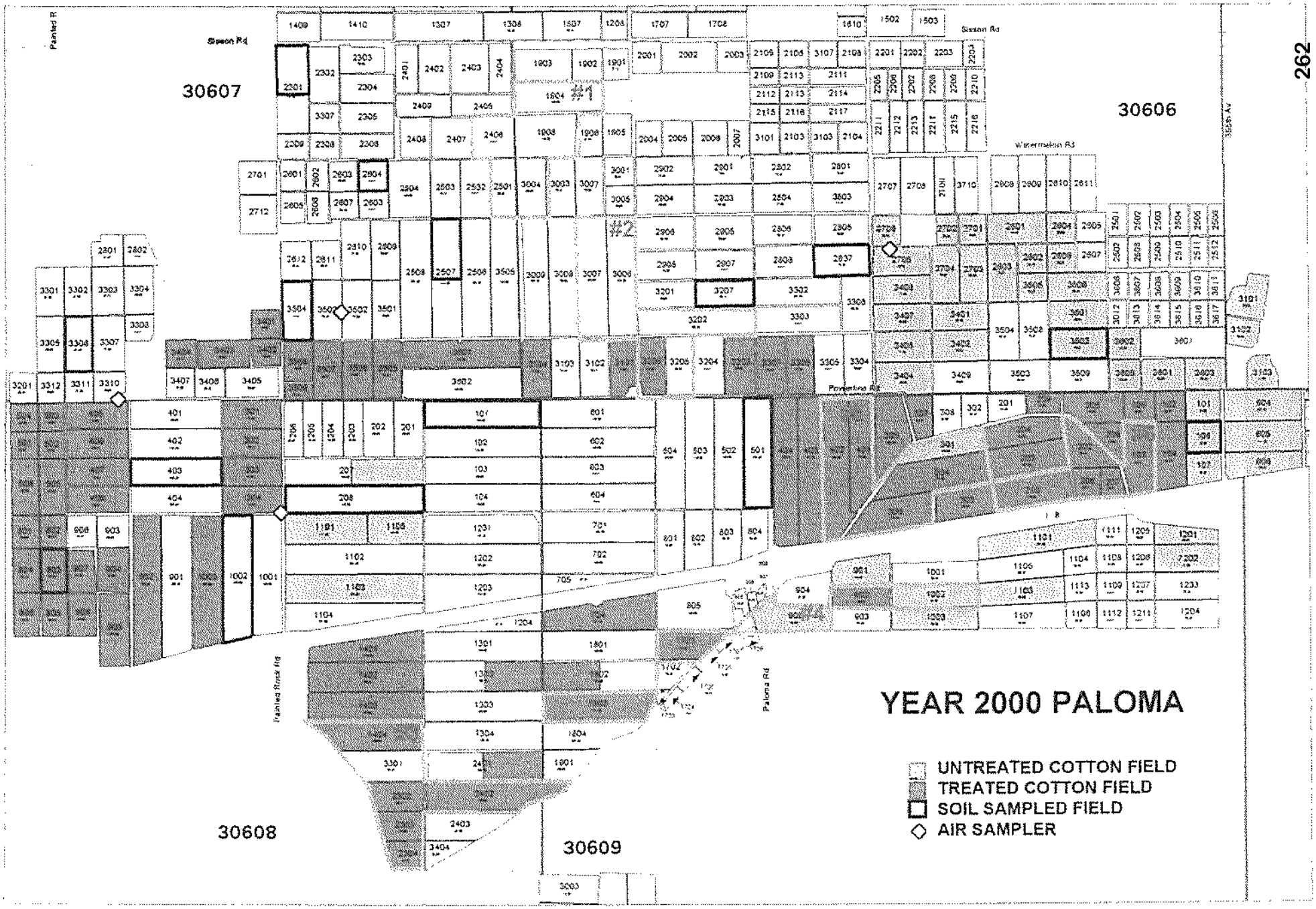


MOHAWK VALLEY
YUMA CO.
~~2,733~~ ACRES
1900 Acres
W PB 4/10/01

YEAR 2000 MARICOPA STANFIELD

UNTREATED COTTON FIELD
TREATED COTTON FIELD
SOIL SAMPLED FIELD




YEAR 2000 PALOMA
UNTREATED COTTON FIELD
TREATED COTTON FIELD
SOIL SAMPLED FIELD
AIR SAMPLER
30607
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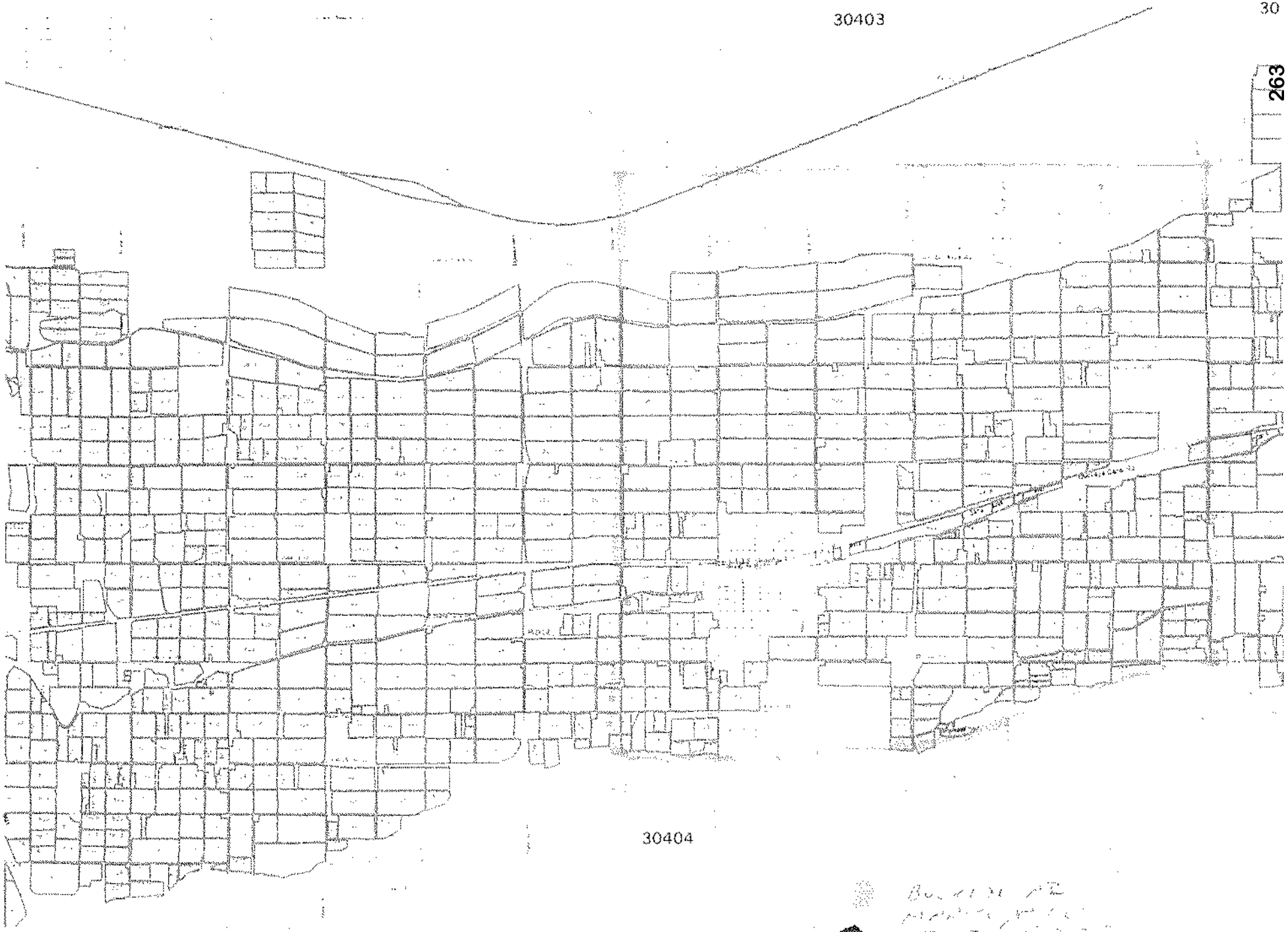
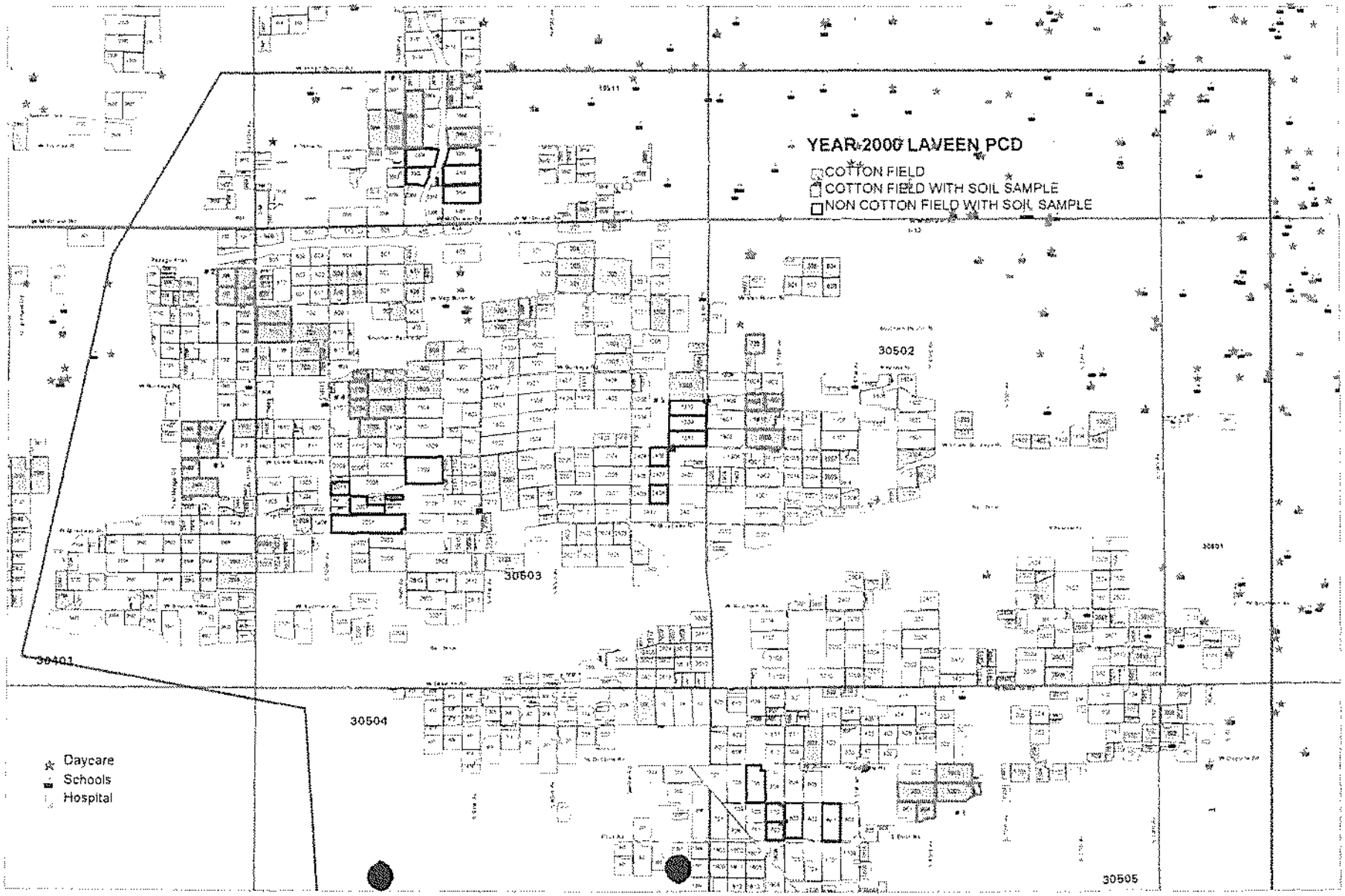
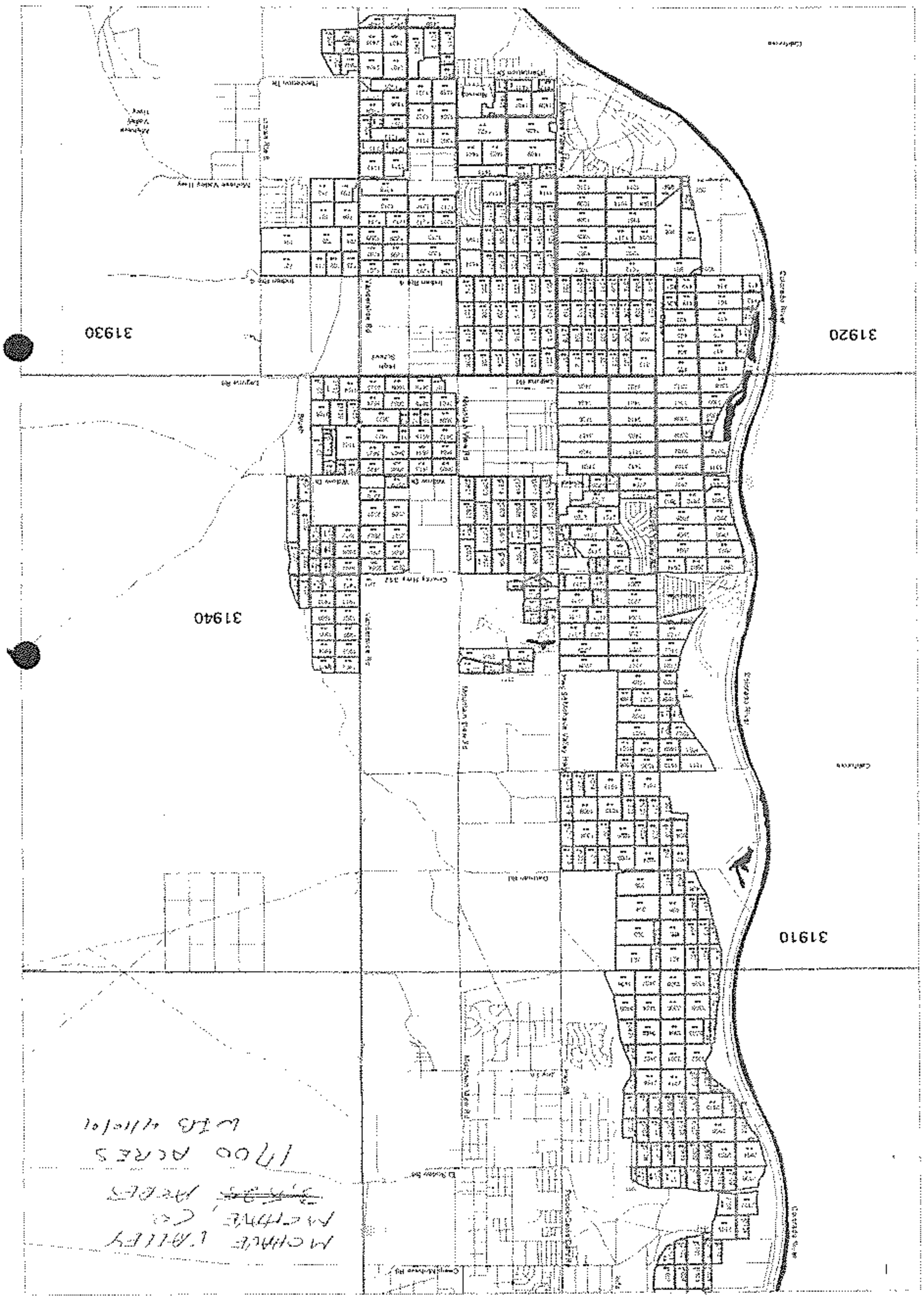
30608
30609
Sisson Rd
Painted R
Watermelon Rd
Powerline Rd
Painted Rock Rd
Paloma Rd
#1
#2



600 ACRES WJB 4/10/01


YEAR 2000 LAVEEN PCD
COTTON FIELD
COTTON FIELD WITH SOIL SAMPLE
NON COTTON FIELD WITH SOIL SAMPLE
30502
30503
30401
30504
30505
Daycare
Schools
Hospital


31930
31920
31940
31910
Colorado River
MOHAVE VALLEY
MOHAVE, CO
ACRES
1700 ACRES
LIB 4/16/01

RECEIVED 9/19/00

Interregional Research Project No. 4
Center for Minor Crop Pest Management

September 14, 2000

TO: Ms. Shanaz Bacchus

FROM: William L. Biehn

SUBJECT: Aspergillus flavus AF36 for Use on Cotton in Arizona - AF36 PROGRAM AREA MAPS

As requested, attached are copies of the areas treated with AF36 in year 2000. These same general areas, Yuma, Paloma, Maricopa/Stanfield and Lareen are planned to be treated in year 2001. The final decisions for AF36 activities in year 2001 will depend on acreage allowable for treatment.

Refer to the attached memo from Larry Antilla to me dated 9/5/2000 for additional details.

WLB:js

Enclosure

shared/judy/bill/bacchus.wpd

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932-8481

ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
3721 East Wier Avenue
Phoenix, Arizona 85040-2933
(602) 438-0059 - Phone
(602) 438-0407 - Fax

Memorandum

September 5, 2000

To: Bill Biehn, IR-4

From: Larry Antilla, ACRPC LA

Subject: AF 36 Program area maps

Enclosed please find two copies of the maps representing AF 36 activities for the year 2000.

The maps represent the four established AF-36 treatment areas. These areas include a second year of treatments, Yuma (Welton/Roll), Paloma and Marieopa/Stanfield. A fourth area, Laveen, was added this year. It has a greater urban interface than the other three as indicated by the number off day care centers, schools and hospitals on the map.

Preliminary discussions are being arranged with grower groups and ginning communities for year 2001 AF 36 activities. Final decisions will depend upon acreage allowable for treatment. We suggest that additional maps listing hospitals, health care centers, etc be provided for EPA following 2001 area treatment decisions. It is however, up to EPA if maps are needed sooner. We do intend to continue to adhere to the buffer zones referenced in our memo of April 21, 1999.

LA/ym

ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL
2403 West Huntington, Suite 101,
Tempe, Arizona 85282-3166
(602) 438-0059
(602) 438-0407 - Fax

April 21, 1999

To : Phil Hutton
Environmental Protection Agency

From : Larry Antilla
Arizona Cotton Research and Protection Council

Subject: Buffer Zones

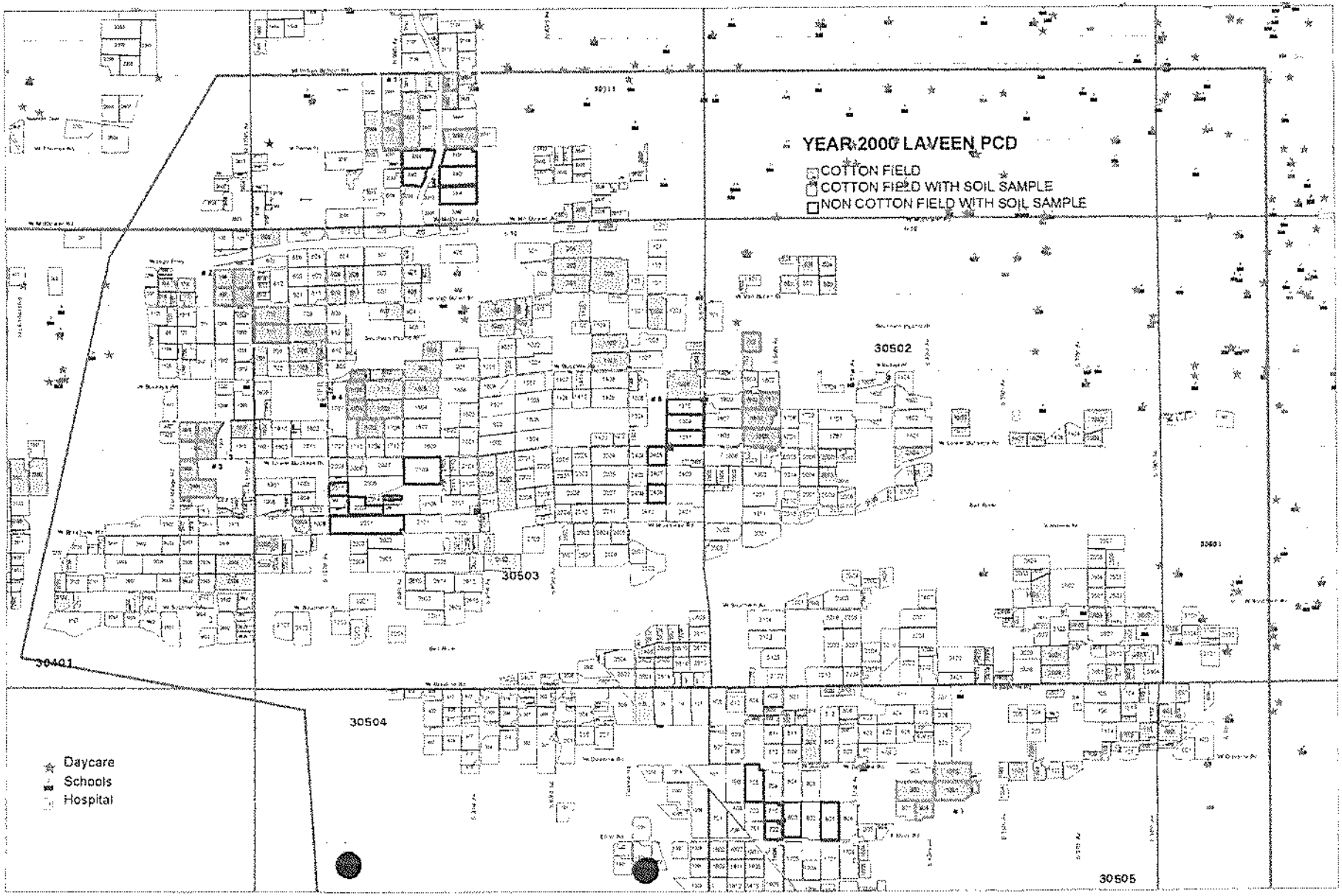
As per today's teleconference relative to Arizona's AF36 Aflatoxin reduction program, we agree to include the following in the operational protocol for Expanded EUP activities on cotton in Arizona in 1999.

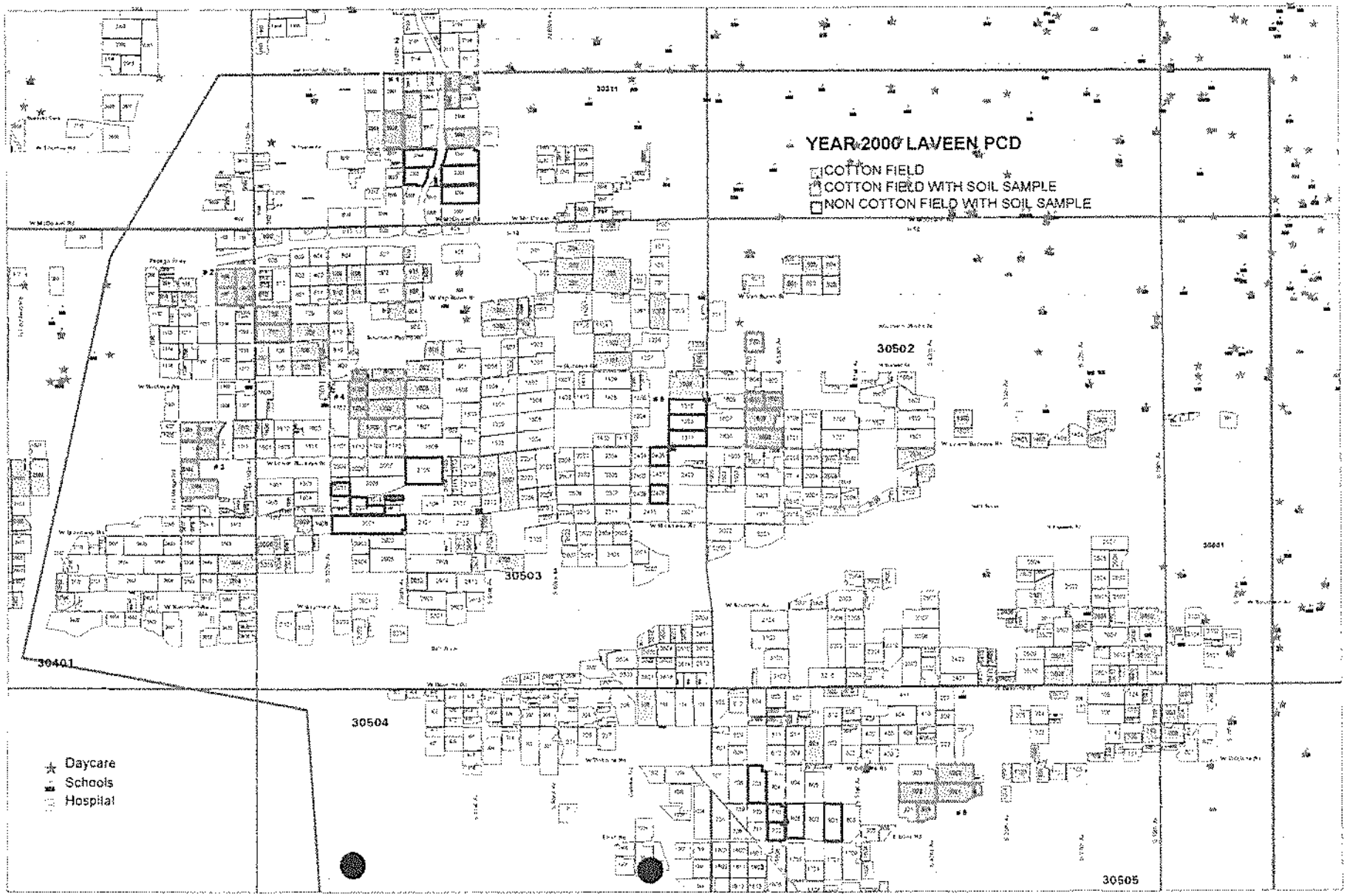
> Establish and adhere to a 400 foot buffer zone for all AF36 treatments with respect to all hospitals, nursing homes, health care and other treatment centers where immune compromised individuals may be found. We will also include all schools and licensed day care centers in the protocol.

If you need additional clarification on the subject please contact me.

Thank you for your consideration of this matter.

AF36\PHutton lt


YEAR 2000 LAVEEN PCD
COTTON FIELD
COTTON FIELD WITH SOIL SAMPLE
NON COTTON FIELD WITH SOIL SAMPLE
30502
30503
30504
30505
Daycare
Schools
Hospital


YEAR 2000 LAVEEN PCD
COTTON FIELD
COTTON FIELD WITH SOIL SAMPLE
NON COTTON FIELD WITH SOIL SAMPLE
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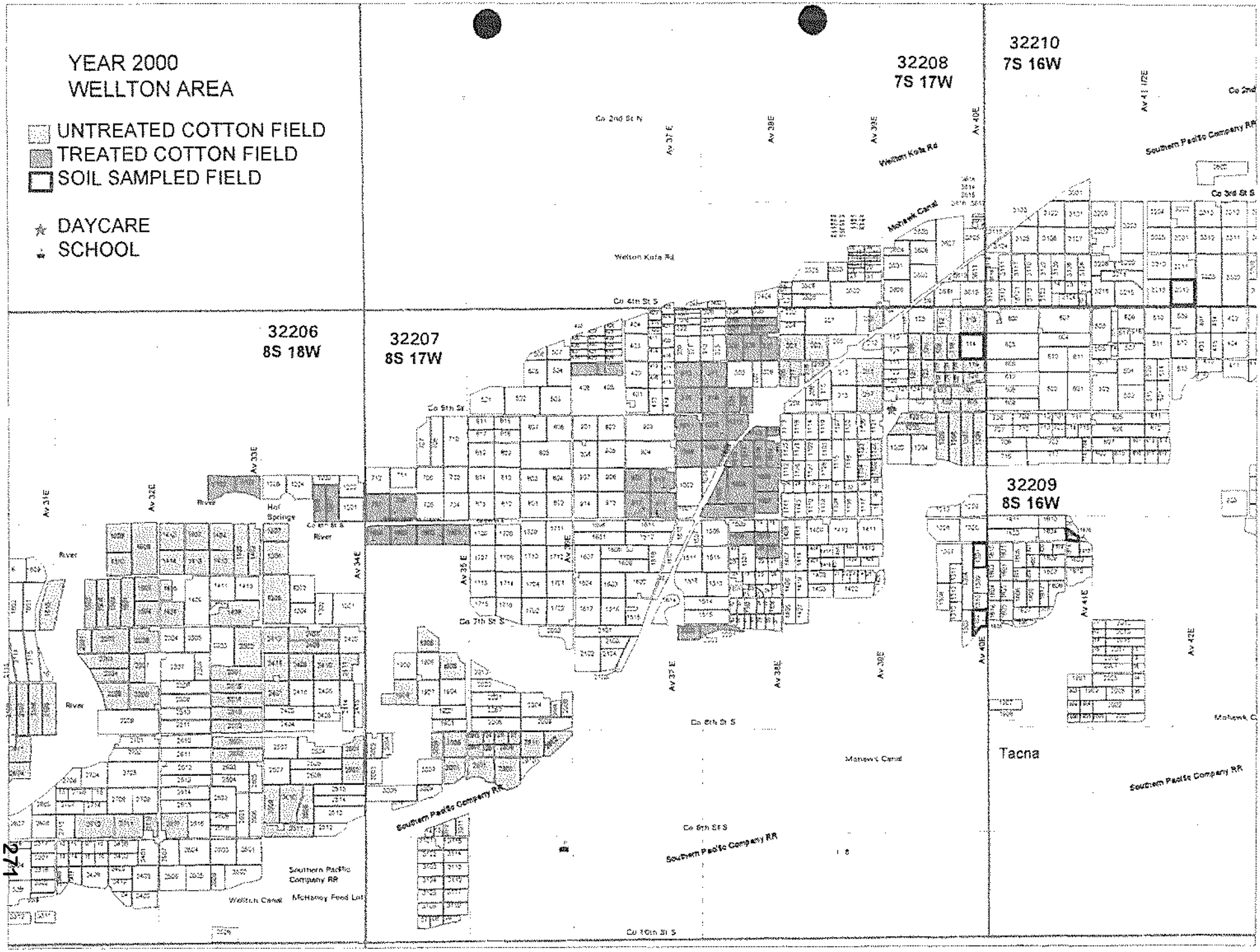
Daycare
Schools
Hospital


YEAR 2000
WELLTON AREA
UNTREATED COTTON FIELD
TREATED COTTON FIELD
SOIL SAMPLED FIELD
DAYCARE
SCHOOL
32206
8S 18W
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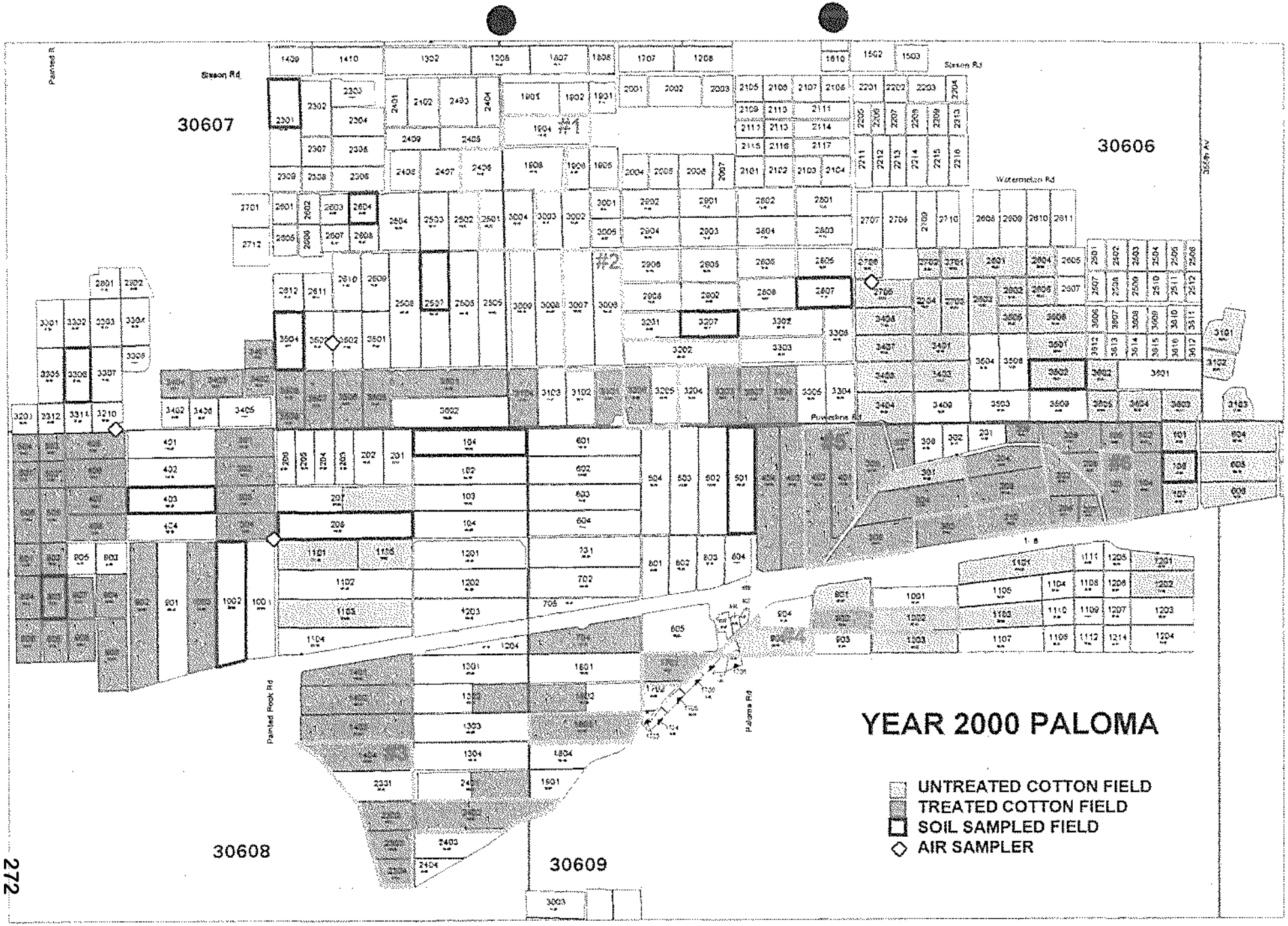
8S 16W
Tacna
Southern Pacific Company RR
Mohawk Canal
Wellton Kofa Rd
McHaney Feed Lot
Hot Springs
River


YEAR 2000 PALOMA
UNTREATED COTTON FIELD
TREATED COTTON FIELD
SOIL SAMPLED FIELD
AIR SAMPLER
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Sisson Rd
Watermelon Rd
Painted Rock Rd
Paloma Rd
#1
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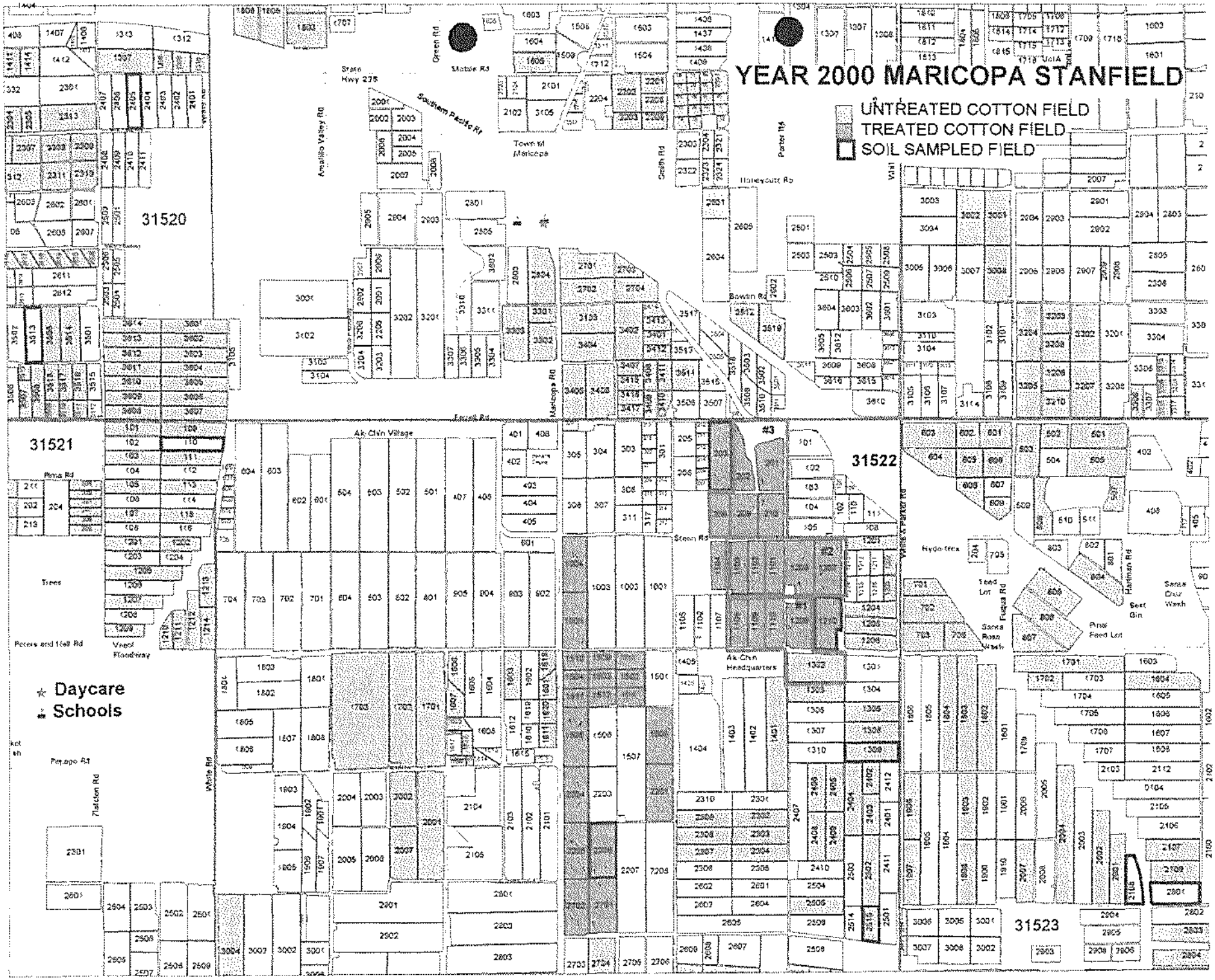
YEAR 2000 MARICOPA STANFIELD
UNTREATED COTTON FIELD
TREATED COTTON FIELD
SOIL SAMPLED FIELD
Daycare
Schools
31520
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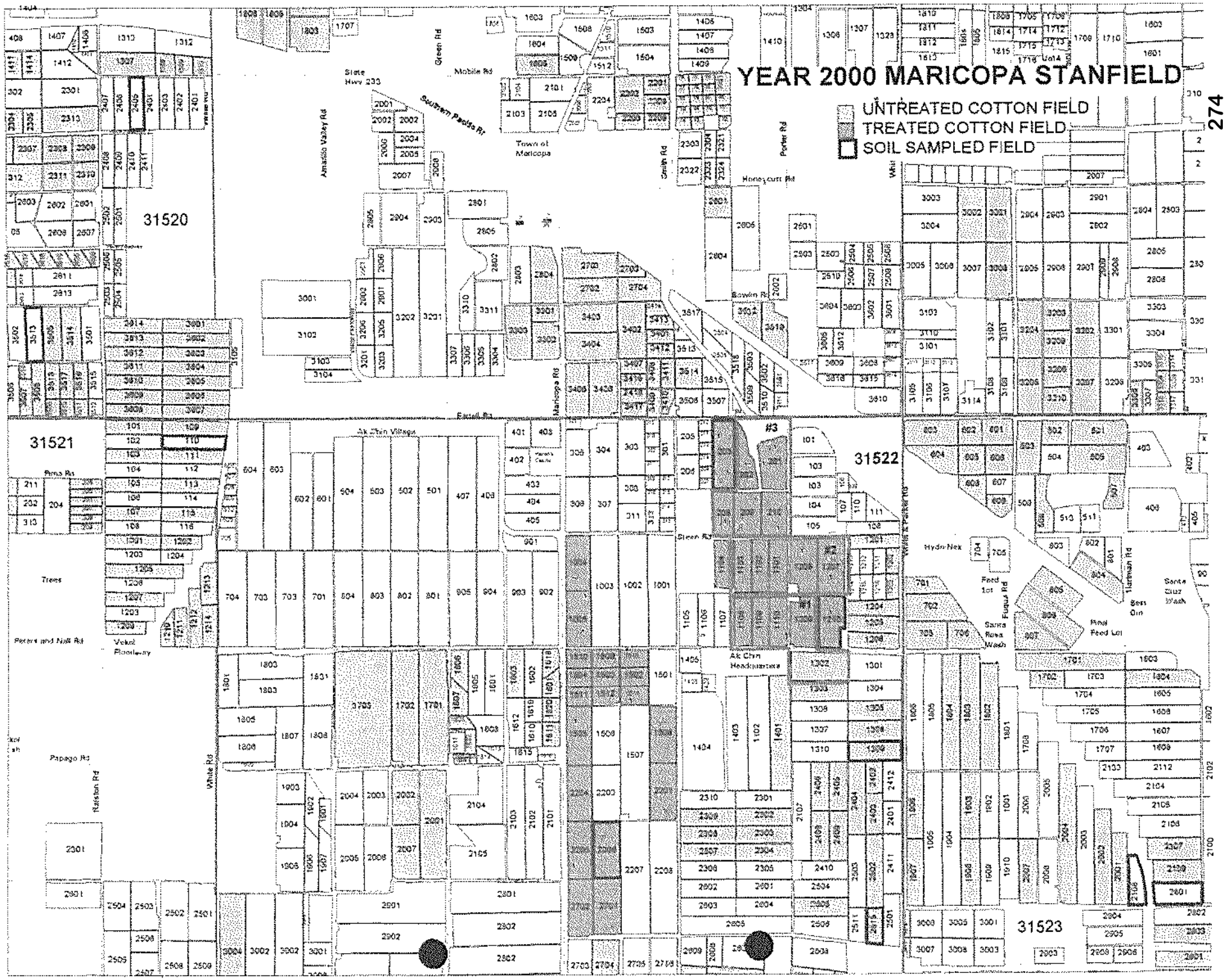
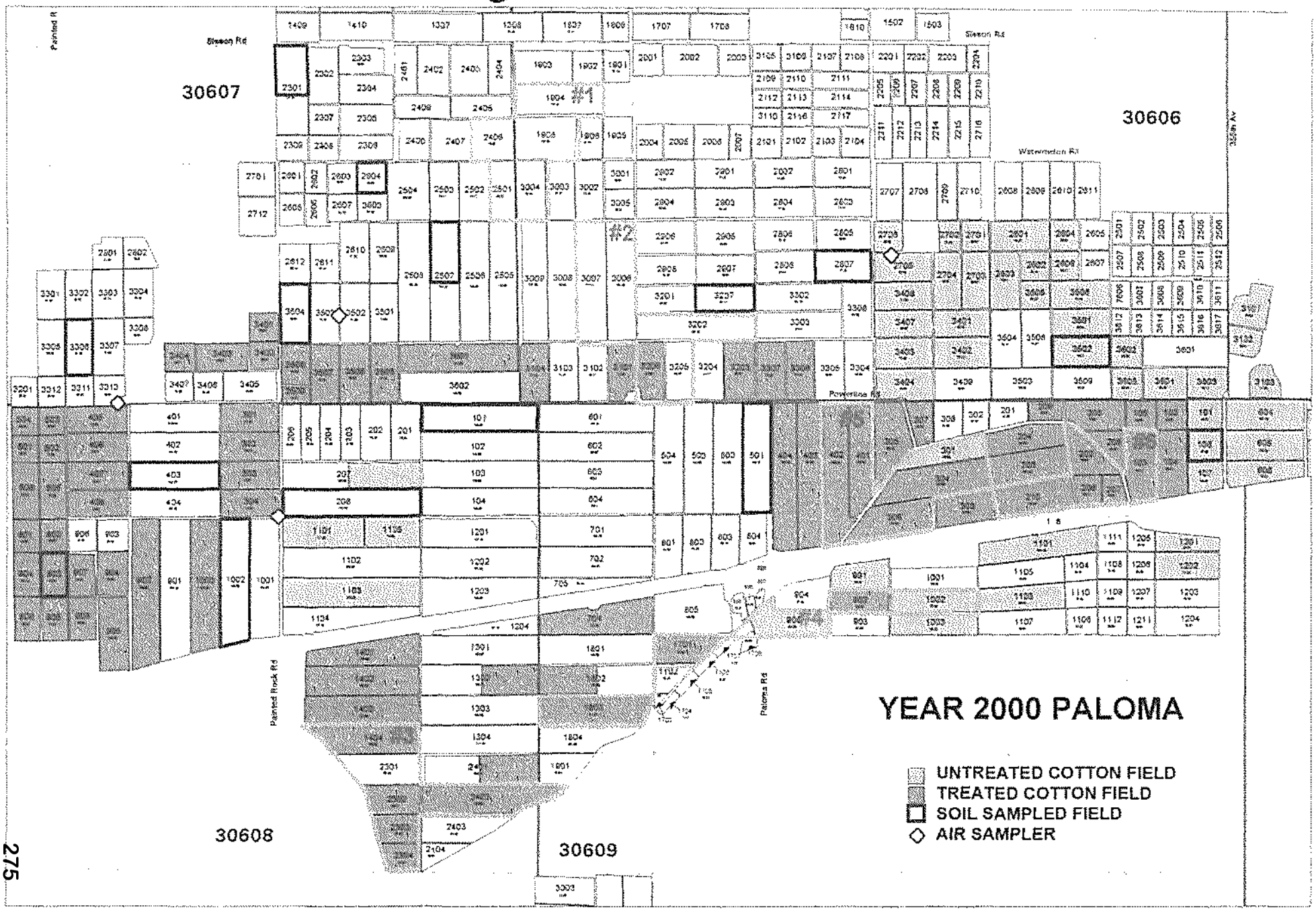
31523
Ak-Chin Village
Ak-Chin Headquarters
Southern Pacific Rd
Amarillo Valley Rd
Green Rd
Smith Rd
Porter Rd
Honeycutt Rd
Bowlin Rd
Steen Rd
Pima Rd
Peters and Hall Rd
Vaeol Floodway
Pepago Rd
Flatiron Rd
White Rd
Hyde-Wex
Feed Lot
Santa Rosa Wash
Pinal Feed Lot
Sext Gin
Santa Cruz Wash
Harman Rd
Fuqua Rd
Trees

YEAR 2000 MARICOPA STANFIELD

UNTREATED COTTON FIELD
TREATED COTTON FIELD
SOIL SAMPLED FIELD

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Powerline Rd
Painted Rock Rd
Paloma Rd
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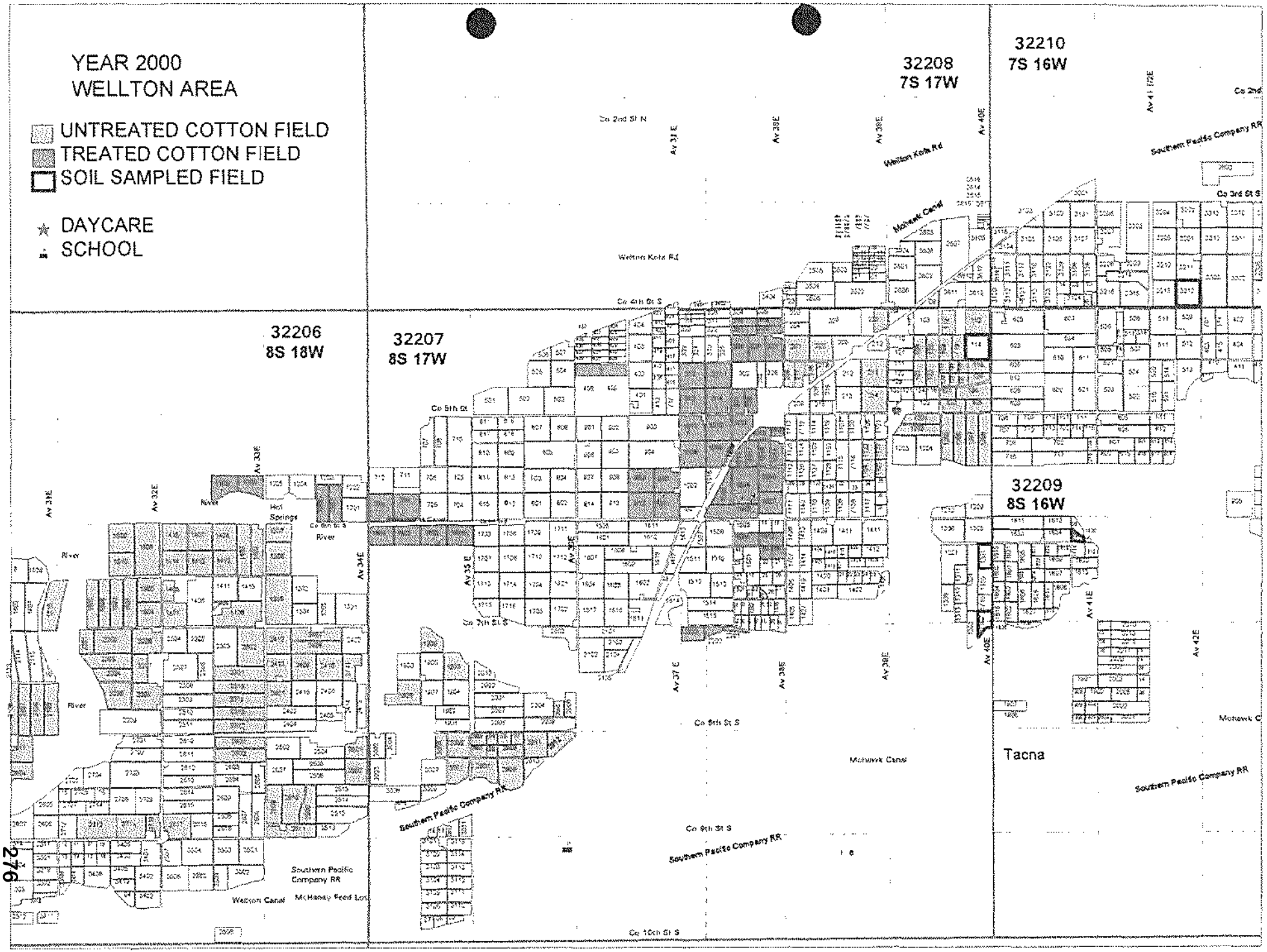
YEAR 2000
WELLTON AREA
UNTREATED COTTON FIELD
TREATED COTTON FIELD
SOIL SAMPLED FIELD
DAYCARE
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32210
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8S 16W
Tacna
Southern Pacific Company RR
Mohawk Canal
Wellton Canal
Wellton Kofa Rd
Co 2nd St N
Co 3rd St S
Co 4th St S
Co 5th St
Co 6th St S
Co 7th St S
Co 8th St S
Co 9th St S
Co 10th St S
Av 31E
Av 32E
Av 33E
Av 34E
Av 35E
Av 36E
Av 37E
Av 38E
Av 39E
Av 40E
Av 41E
Av 42E
River
Hot Springs
McHaney Feed Lot

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Company [illegible]

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Dept./Floor/Suite/Room

City [illegible] State [illegible] ZIP [illegible]

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United States Department of Agriculture
Agricultural Research Service
Mid South Area Southern Regional Research Center
1100 Robert E. Lee Boulevard
P.O. Box 19687
New Orleans, Louisiana
70179-0687

June 23, 2000

Ms. Shanaz Bacchus
Regulatory Action Leader
USEPA, BPPD/OPP (7511C)
Crystal Mall #2, Room 902
1921Jeffersion Davis Highway
Arlington, VA 22202
Phone: 703-308-8097
FAX: 703-308-7026

Dear Ms. Bacchus:

Dr. W. L. Biehn of the IR-4 project asked me to send a copy of the enclosed manuscript by courier for delivery on Monday June 26th. This manuscript is a preliminary draft that we hope to refine for submission for publication in the next few months. I will discuss aspects of the studies covered by the manuscript in our meeting on June 27th. I look forward to our discussions on Tuesday.
Best Regards.

Sincerely,

Peter J. Cotty
Research Plant Pathologist
Food and Feed Safety Research

ENCLOSURE

AGENDA

EPA PREREGISTRATION MEETING

MICROBIAL PRODUCT: ASPERGILLUS FLAVUS AF36 ON COTTON IN ARIZONA

Tuesday June 27, 2000 at ~~10:30 AM~~ 1:00 PM WJBiehn
Room 912
EPA Crystal Mall #2
1921 Jefferson Davis Highway, Arlington, VA

1. Introductions
   Dr. Phillip J. Wakelyn

2. Airborne spore counts of Aspergillus flavus in treated and untreated fields
   Dr. Peter Cotty

3. Aspergillus flavus in Natural Habitats
   Dr. Peter Cotty

4. Toxicity testing and other data needed for registration
   a) Acute Pulmonary Toxicity/Pathogenicity Requirement in Mammals
   b) Avian Acute Oral Toxicity/Pathogenicity Requirement
   c) Avian Acute Pulmonary Toxicity/Pathogenicity Requirement
   d) Honey Bee Testing Requirement

5. Other items
   a) Options for use and testing of AF36 in the year 2001 in Arizona
   b) Discussion

Seasonal changes in the quantities of *Aspergillus flavus* and other propagules in the air over Arizona cotton fields

[1]C.H. Bock and P.J. Cotty

USDA-ARS-SRRC, 1100 Robert E. Lee Boulevard, New Orleans, LA 70124. [1]Current address of first author: Centre for Plant Biodiversity Research, CSIRO-Plant Industry, GPO 1600, Canberra, ACT 2610, Australia.

ABSTRACT

Airborne *Aspergillus flavus* was monitored continuously with two Burkard cyclone samplers from May 1997 to March 1999 at two sites in Arizona surrounded by commercial agriculture. One sampler was initially at the center of 65 ha of cotton treated June 2, 1997 with an atoxigenic vegetative compatibility group (VCG) of *A. flavus* and the second sampler was about 1 km from the treated field. Both fields went through typical crop rotations. Propagules in the size range of conidia were collected by the cyclones at levels comparable to those collected by impaction onto 0.8 μm pore membranes. Quantities of both total fungi and *A. flavus* did not differ (P=0.05) between the two sites. Total fungal propagules ranged from 17 to 667 m^{-3} and from 9 to 1,277 m^{-3}, at the non-treated and treated sites respectively. Counts of *A. flavus* ranged from <1 to 406 m^{-3} and <1 to 416 m^{-3} and *A. flavus* comprised 1 to 46% and <1 to 51% of the total cultured fungi at the two sites, respectively. Peaks in both total fungal propagules and *A. flavus* propagules coincided with area-wide boll maturation and cotton harvest (Julian day 251-321). The S strain was most frequent between May and August. In other months, the L strain accounted for up to 100% of the *A. flavus* sampled. The applied VCG accounted for 0-47% of the L strain at the untreated site and 5-75% at the treated site. The applied VCG was a greater proportion of *A. flavus* at the treated site than at the non-treated site (P=0.01). Modified rotorod samplers collected viable *A. niger*, but little *A. flavus*. Large quantities of *A. flavus* occurred in the soil (up to 34,474 propagules g^{-1}) of cotton fields and on cotton plant parts and debris (up to

272,461 propagules g^{-1}) adjacent to the cyclone samplers. These data suggest that *A. flavus* is a major constituent of the air associated with cotton fields in southwest Arizona at certain times of the year. Although application of atoxigenic *A. flavus* altered the proportion of strains and VCGs in the aerial mycoflora, it did not alter the total quantity of *A. flavus*. Dispersal of *A. flavus* between fields suggests atoxigenic fungi will be most effective in area-wide management programs.

Additional keywords: aflatoxin management; agricultural dust.

Aspergillus flavus Link can infect cottonseed and other food and feed crops under specific environmental conditions (Deiner *et al.*, 1987). Concern for *A. flavus* infections largely stems from fungal production of aflatoxins, potent natural carcinogens. To minimize the risk of toxin carryover to man or livestock, crop aflatoxin content is strictly regulated in many countries (Park *et al.*, 1988).

One approach to limit aflatoxin contamination in cottonseed is application of strains of *A. flavus* that do not produce aflatoxins (atoxigenic strains) to competitively exclude the aflatoxin producing strains (Cotty, 1992; 1993; Cotty, 1994a). One atoxigenic strain is being tested under an EPA approved experimental use permit (69224-EUP-1) on farms in southwest Arizona to assess efficacy in controlling aflatoxin contamination of cottonseed in field scale systems. Atoxigenic strains of *A. flavus* have been effective in experimental plots with peanut (Dorner *et al.*, 1992), corn (Brown *et al.*, 1991, Dorner, 1999), and cotton (Cotty, 1994a).

Although aflatoxin contamination is reduced by application of atoxigenic strains (Cotty, 1994a), there is no basis on which to gauge the overall effect of treatments on quantities of *A. flavus* propagules in the air. Furthermore, the seasonal dynamics of airborne *A. flavus* in cotton production in southwestern Arizona has been incompletely described. Atoxigenic strain applications seek to competitively exclude aflatoxin producers and optimal application of the biocontrol agent is dependent on the community dynamics of aflatoxin-producing *A. flavus*

strains. Lack of information on seasonal dynamics of air-borne conidia of *A. flavus* precludes a rational approach to delimiting optimal periods over which fields may be treated. Dispersal of an atoxigenic strain prior to the presence of aflatoxin-producers in the air flora will give the biocontrol agent preferential exposure to potential food sources and thereby increase its biocompetitive potential.

In general, there is little information on seasonal changes in aerially dispersed *A. flavus* propagules in agriculture. Epidemiological studies have investigated influences of factors on infection of and aflatoxin formation in cottonseed, (Ashworth *et al.*, 1969a; Ashworth *et al.*, 1969b; Ashworth *et al.*, 1971; Marsh *et al.*, 1973; Diener *et al.*, 1987; Lee *et al.*, 1989) and the production and dispersal of propagules at specific times in cotton (Lee *et al.*, 1986) or in other crops (Bothast *et al.*, 1978; Holtmeyer and Wallin, 1980; Holtmeyer and Wallin, 1981; Olanya *et al.*, 1997). Peaks in quantities of *A. flavus* are found in summer months, but previous studies have not described annual cycles of *A. flavus* in the air spora. The quantity of *A. flavus* in the air in relation to other fungal propagules in cultivated desert environments of southwest Arizona is also unknown, although *A. flavus* is a major constituent of the airspora in other environments (Morrow *et al.*, 1964). Dynamics of interactions among air-borne fungi have not been investigated.

In order to expand available information on characteristics of production and dispersal of conidia of *A. flavus* in southwest Arizona we sampled air for microbiological propagules for two years at two sites approximately 1 km apart. Fields surrounding one site were initially planted with cotton and treated with an atoxigenic strain of *A. flavus*. Fields surrounding the second site were not treated and initially planted to barley. Information on fungal dynamics of value in developing application strategies for the aflatoxin biocontrol agent in cotton-producing regions of Arizona were sought.

MATERIALS AND METHODS

Cyclone samplers. Two Burkard Cyclone Samplers (Burkard Manufacturing Co. Ltd., Rickmansworth, Hertfordshire, England) were operated continuously from May 1997 to March 1999 (Fig. 1). One sampler was initially in the center of 65 ha of cotton treated with atoxigenic *A. flavus* (strain AF36; Cotty and Bayman, 1993) in 1997 (June 2). The field (16 ha) southeast of the sampler was also treated in 1996. The second sampler was about 1 km from the nearest treated field (Fig. 2). Fields surrounding the samplers remained in commercial agriculture and were rotated through several crops (Table 1).

The Burkard cyclone sampler operates by drawing air through an orifice at a rate of 16.5 L min^{-1} and depositing the particles in still air in a microfuge tube at the base of the cyclone stream. Sampler performance was monitored with a hot wire anemometer (Model HHF51, Omega Engineering, Stamford, CT) to ensure air was drawn at the correct rate. Particle size sampling efficiency has been characterized (Emberlin and Baboonian, 1995) and is excellent for particles with the size range of *A. flavus* spores (3-10 um). In this study samples were taken weekly and each sample was weighed, suspended in sterile distilled water, dilution plated on agar media, and incubated at 31 C. Total colony forming units (CFUs) of all fungi and the number of *A. niger* colony forming units (CFUs) were counted on PDA and 5/2 agar (Cotty, 1989), and the number of *A. flavus* colonies was counted on modified rose bengal (MRB) agar (Cotty, 1994b). PDA and 5/2 agar were amended with streptomycin (0.05 g l^{-1}) and chloramphenicol (0.05g l^{-1}). Fungal propagules m^{-3} air were calculated. For comparisons between total fungi and quantity of *A. flavus* counts based on the 5/2 plates were used. Bacterial colony counts were made on unamended nutrient agar. After sub-culturing on 5/2 agar for 7 days at 31 C all *A. flavus* isolates were assigned to either the S or L strains on the basis of morphological criteria (Cotty, 1989). A total of 3,307 *A. flavus* isolates (c.25 per sample) were sub-cultured and characterized to strain. The proportion of *A. flavus* accounted for by the applied atoxigenic strain was estimated by vegetative compatibility group (VCG) analysis

(Cotty, 1994a) of the first 20 L isolates sampled every 4 weeks (720 isolates total). The growers provided cropping history of the four 40-acre fields immediately adjacent to each sampler.

The size range of particles sampled by the cyclone sampler was determined microscopically (Olympus X100 S Plan, dry objective, ocular micrometer) for seven separate samples. The sample was suspended in sterile distilled water and the first 100 particles observed during an 80 μm-wide transect across the slide were measured. In a similar manner, conidia from 7-day old cultures of *A. flavus* (AF36) grown on 5/2 agar were measured to ensure conidia of this isolate fell within the size range of the particles being sampled by the Burkard cyclone sampler. The length and width of both fresh conidia suspended in sterile distilled water, and conidia dried in an oven at 50 C for 4 h were measured. Dried conidia were dusted directly onto slides. Coverslips were used. Conidia were dried prior to measurement in an attempt to simulate dehydration of conidia in the Sonoran-desert of western Arizona.

Filter membranes were used to further characterize propagules of *A. flavus* sampled by the cyclone sampler. Two samples were suspended in 5 ml sterile distilled water and repeatedly filtered through polycarbonate screen membranes (Poretics Corporation, Livermore, California) with decreasing pore size (control - not filtered, 20, 12, 5, and 3 um pore size). These filters are perforated with precise pore size and have sharp cut-off retention characteristics (Ballew, 1997). The proportions of *A. flavus* propagules passing through each filter were determined by dilution plate technique.

Filter impaction. To compare efficiency of sample catches of the Burkard cyclone sampler with a membrane impaction technique, air pumps (12 v DC, P/N MTR1002, Gast Manufacturing Corporation, Benton Harbor, Michigan) fitted with membrane based field monitors for contamination analysis (pore size 0.8 um, Millipore Corporation, Bedford, Massachusetts) were operated at 16.5 L min^{-1} alongside the cyclone samplers for different periods. After sampling, the filter was removed and washed three times in 2 ml sterile distilled water. Three 0.1-ml aliquots of each washing were plated onto MRB. The membrane filter was also placed face up on the agar. The quantity of *A. flavus* m^{-3} air sampled was calculated. A cyclone sampler was

operated simultaneously with the impaction samplers and the cyclone samples were processed as previously described except the sample was suspended in 0.5 ml sterile distilled water and the entire volume was plated. Comparisons were made on three dates. For each date, three replicate samples were taken. Replicates consisted of one cyclone sample and three impaction samples taken simultaneously.

Rotorod samplers. The efficiency of rotorod samplers (Perkins, 1957) in collecting *A. flavus* propagules was also tested. Due to the inherent difficulty of identifying *A. flavus* based on spore morphology, modifications to allow culturing of the fungus were necessary. The usual "sticky" impaction surfaces of vaseline or silicone grease generally used for entrapping spores may be toxic to fungi and are not soluble in water and thus are not readily amenable to dilution plate technique. A water-soluble material was developed. A mixture of carboxy-methylene cellulose (CMC, 14 g), Glycerol (20 ml) and water (40 ml) formed a stiff, tacky grease that spread evenly on 0.1 cm dia. quartz glass collecting rods (Friedrich and Dimmock Glassworks, Millville, New Jersey). The coating was applied by sliding the rod between index finger and thumb. On plastic or metal the coating coalesced, preventing even distribution on the sampling face. Sampling characteristics were compared with silicone grease by operating the rotorods in flow hoods while gently tapping an upturned plate to dislodge conidia. One rod was coated with the CMC coating, the other with silicone grease. The rods (2.5 cm long) were removed after operation and the number of conidia sampled counted on each rod. The glass rods (16 cm apart) were placed in 1 mm holes drilled in the ends of the plastic tube of a ball point pen. Locking nuts were glued on the end and used to hold the rods in place. Attached to the center of the plastic tube was the bevel with lock nut to attach the tube to the motor spindle. The apparatus rotated at 3000 rpm.

For field sampling the rotorod motors (12 v DC, Model Number 2M197, Dayton Electric Manufacturing Company, Niles, Illinois) were supported within 10 cm (internal diameter) polyvinylchloride pipe joints (Fig. 3). Three motors were placed on each pipe by using a four-

way pipe split with 50 cm sections of tube placed in the horizontal outlets and motors placed in the open ends of the pipes. Thus each experiment had three replications. The base of the piping was buried in the ground. Sampling period was investigated by operating the motors for 2 and 4-h periods. This was repeated twice. In addition samples were taken at different locations and times.

Weather data. Weather data was obtained from the Roll station of the Arizona Meteorological Network (AZMET) at http://ag.arizona.edu/azmet/24html (files 2498ew.txt and 2499ew.txt). Details of the equipment and measurement protocols used at the Roll station may be found at this site. The mean weekly data for temperature (maximum, minimum, and mean); rainfall and humidity were used to describe the weather conditions for the duration of the sampling period from May 1997 to March 1999.

Soil and surface samples. In late June and October of 1997 samples of soil, leaves, leaf litter, and boll material were taken from fields adjacent to the cyclone sampler in the treated area. Five replicate samples were taken at random points within 50 m of the sampler. Soil samples comprised the surface 2-3 mm of soil scraped from a 2 m length of row. The lower and oldest leaves (100 g) were collected in June and in October chemically defoliated (as per normal commercial practice) leaves (100 g) were collected from the ground. Boll samples (20 bolls/sample) were taken at random locations within 50 m of the sampler. In June bolls were immature and unopened. In October bolls were fully mature and open. Samples were taken from the middle to bottom of the canopy.

In June and October of 1998, soil samples were taken from the four fields surrounding each cyclone sampler. Samples were taken along a diagonal across each field starting at that site's sampler at 25, 50, 150, 250 and 400 m, as described above.

Soil samples were mixed thoroughly and a subsample (5-20 g) was suspended in 50 ml sterile distilled water, agitated vigorously for 10 min, and subjected to dilution plate technique on MRB agar. Leaf material (5-8 g in 200 ml), leaf litter (5-17 g in 500 ml) and bolls/locules (10-25 g in 500 ml) were processed similarly. CFUs of *A. flavus* were counted and CFUs g^{-1} of material calculated. Strain (S/L) composition and the proportion of the L strain in the applied VCG was estimated as for the cyclone samples.

Data analysis. Data was analyzed using Statistica V3.0 and SAS V8.0. Comparisons between microbe counts at treated and untreated sites were with t-tests. These included quantitative comparisons of total fungi, *A. flavus*, *A. niger*, bacteria, S strain, and the applied atoxigenic VCG. Correlation analyses were used to relate total fungal propagules with those of *A. flavus*, and to investigate the relationship between rotorod sampling methods (silicon grease vs CMC). Analysis of variance was used to test all multiple comparisons (catches of *A. flavus* by

filter impaction vs cyclone sampler, catches of *A. flavus* by rotorods, and propagule counts and characteristics from soil, bolls and leaves). Tukey's HSD test was used to separate the means. Standard deviations were calculated for the size ranges sampled by the Burkard cyclone samplers, and the numbers of CFUs obtained after filtering the cyclone sampler catches.

RESULTS

Cyclone samplers. The MRB agar tended to grow more *A. flavus* colonies than either the PDA or 5/2 media (Table 1). However, except for the PDA vs MRB at the untreated site, t-tests showed no significant differences, probably on account of the large variances associated with each of these samples. Counts of total fungal propagules were made on 5/2 (a mean of 139.5 and 120.3 propagules m^{-3} at the treated and untreated sites, respectively) and PDA (a mean of 119.8 and 89.6 propagules m^{-3} at the treated and untreated sites, respectively). As there was no significant difference between the counts on the two media (t-test, P=0.05), only those for 5/2 are presented.

The weight of material collected by the cyclone samplers varied from 0.001 g to 1.0018 g per sampling period (Fig. 4A). However, the quantity exceeded 0.2 g on only two occasions. Numbers and characteristics of propagules sampled from the two sites were similar (Fig. 4B). During 1997 (May-December) the total fungal propagules collected at the non-treated site ranged from 17 to 667 m^{-3}, and at the treated field from 9 to 1277 m^{-3}. During 1998-99 (January 1998 – March 1999) total fungal propagules ranged from 2 to 652 and 2 to 412 propagules m^{-3}, respectively at the two sites. Over the same time periods counts of *A. flavus* in 1997 ranged from <1 to 406 and <1 to 416 m^{-3} at the treated and untreated sites respectively, and in 1998-9 the numbers ranged from <1-361and <1-117, at the two sites respectively. On 5/2 agar *A. flavus* comprised <1 to 46% of the total cultured fungi at the untreated site and <1 to 51% at the treated site in 1997 (Fig. 4C), and <1to 41% of the total cultured fungi at the non-treated site and <1 to 44% at the treated site in 1998. Greatest numbers of both total fungal propagules and *A. flavus* propagules occurred between JD 177 in 1997 to JD 43 in 1998 and JD 191 in 1998 to JD 8 in

1999. In both years the peaks coincided with JD 251-32. Very low numbers of all propagule types were sampled between mid January and May (sample weights at these times also tended to be lowest).

There were no significant differences (t=ns, P = 0.05) between the two sites in either mean number of total propagules m^{-3} nor propagules of *A. flavus* m^{-3}. A mean of 139.5 and 120.3 total fungal propagules m^{-3} were sampled at the treated and untreated sites respectively (t=ns, P=0.05). *Aspergillus flavus* propagule counts were 28.6 and 29.7 m^{-3} at the treated and untreated sites, respectively (t=ns, P=0.05). Differences between catches at the two sites in the quantity of *A. flavus* were not detected following application of the atoxigenic VCG. The quantity of *A. flavus* collected by the treated site sampler in 1997 (JD194-343) differed from that collected in 1998 (JD 194-341) (100.2 versus 19.3 propagules m^{-3}, t=2.4780, df=17, P=0.01). All four fields surrounding the sampler at the treated site were rotated from cotton in 1997 to wheat in December 1997 and then to lettuce during the 1998 period in question. At the untreated site samplings did not differ between these two periods (53.3 propagules m^{-3} and 54.2 propagules m^{-3}, t =ns, P=0.5). These relationships were similar for total numbers of propagules collected (314.3 and 103.1 propagules m^{-3} at the treated site in 1997 and 1998, respectively, t=2.5603, df=17, P=0.01, and 194.8 and 99.8 propagules m^{-3} at the untreated site, t=ns, P=0.05, respectively).

Correlation analysis showed a strong correlation between total number of fungi sampled and the number of *A. flavus* propagules at the treated site (r=0.9515, 152 df, P<0.001). At the untreated site there was also a positive correlation (r=0.2294, 152 df, P<0.05), although it was less pronounced. Thus conditions favoring production and dispersal of *A. flavus* were conducive for other fungi which increased in number at similar times.

Aspergillus niger propagules were also collected throughout the sampling period. Counts of *A. niger* were made on 5/2 (a mean of 33.9 and 23.9 propagules m^{-3} at the treated and untreated sites, respectively) and PDA (a mean of 26.2 and 21.1 propagules m^{-3} at the treated and untreated sites, respectively), as the MRB inhibited growth of *A. niger*. As there was no significant

difference between the counts on the two media (t=ns, P=0.05), only those for 5/2 are given. The counts followed trends similar to *A. flavus* with peaks of catches occurring during summer and autumn and with very low numbers during the winter. Propagule numbers of *A. niger* ranged from 0–273 propagules m^{-3}. The relative proportions of *A. niger* and *A. flavus* are shown in Fig. 4D. Over the sampling period there were no significant differences (t=ns, $P = 0.05$) between the two sites in mean number of *A. niger* propagules m^{-3}. However, the quantity of *A. niger* collected by the treated site sampler in 1997 (JD194-343) differed from that collected in 1998 (JD 194-341) (133.2 versus 15.7 propagules m^{-3}, t=4.2813, df=12, P=0.001). The quantity of *A. niger* collected by the untreated site sampler in 1997 (JD194-343) also differed from that collected in 1998 (JD 194-341) (62.7 versus 18.7 propagules m^{-3}, t=2.5962, df=17, P=0.009).

Large quantities of bacteria were sampled throughout the two-year study (Fig 4E). The number of bacterial propagules exceeded fungal propagules at all times ranging between ca. 5000 and over ca. 50000 propagules m^{-3}. The counts appeared to be greater in the summer periods, with lower numbers sampled during the winter. There were no significant differences between the two sites in mean number of bacteria m^{-3} (2207 and 2364 propagules m^{-3} sampled at the treated and untreated sites respectively (ns, t=test, P=0.05). The quantity of bacteria collected by the treated site sampler in 1997 (JD194-343) differed from that collected in 1998 (JD 194-341) (1882 vs 768 propagules m^{-3}, t=2.2433, df=19, P=0.018). However, the quantity of bacteria collected by the untreated site sampler in 1997 (JD194-343) was not significantly different to that sampled in 1998 (JD 194-341) (4195 versus 2335 propagules m^{-3}, t=ns, P=0.05). Other fungi (including *Fusarium* spp., *Alternaria* sp. and *Cladosprium* sp.) were sampled but counts and identifications were not made on these species which were generally individually less numerous than either *A. flavus* or *A. niger*.

Both S and L strain isolates of *A. flavus* were detected at both the treated and untreated sites (Fig. 5A). Overall, there was a greater proportion of the L strain at the treated site (80.2%) compared to the untreated site (68.5%, t=2.5390, 135 df, P=0.006). There was distinct seasonality in the incidences of the S and L strains with the L strain most abundant from

September through December. At the treated site 81.3% and 74.3% of the *A. flavus* was L strain between JD 147 and 360 in 1997 and 1998, respectively (t=ns, P=0.05), and at the untreated site over the same period 68.9 and 63.1% was L strain, respectively (t=ns, P=0.05). Greatest quantities of S occurred between May and August both years (35.7-96.0% S (1997) and 28.0-100% S (1998) at the untreated site and 4.5-100% S (1997) and 16.7-84.0% S (1998) at the treated site). The proportion of S at the treated site between May and August (JD 147-243) in 1997 (30.5%) differed from that present between September and December (JD 148-365) (3.9%), (t=4.16, 14 df, P=<0.001). Similar differences occurred in 1998 (38.6% versus 15.5%, t=2.96, 19 df, P=0.004) at the treated site and in both years at the untreated site (54.7% versus 5.41% in 1997 (t=6.2410, 13 df, P=<0.001) and 56.5% versus 17.2%, in 1998 (t=4.88, 17 df, P=<0.001)). The applied atoxigenic VCG belongs to the L strain, and accounted for 0-47% of the total L strain sampled at the non-treated site, and 5-75% at the treated field (Fig. 5B). The applied atoxigenic VCG was more prevalent in the air at the treated site than at the untreated site (t=-3.2041, 32 df, P<0.01).

Cropping history. During the sampling period various crops were grown in the fields adjacent to the two cyclone samplers (Table 2). At the treated site the four fields surrounding the sampler were rotated from cotton to wheat and then to lettuce and back to wheat. Cotton was only present at the treated site during 1997. All four fields surrounding the sampler at the untreated site were rotated from barley to cabbage and then to cotton followed by wheat. The two sites only had the same crop (wheat) from December 1998 through March 1999. During the 1998 sampling period the non-treated site was planted to cotton, although the early cotton season was very cool resulting in poor crop development and one of the lowest yielding Arizona crops in history.

Weather data. Data from the AZMET station at Roll (Fig. 6) indicate that in both 1997 and 1998 maximum daytime temperature was greatest during the summer between JD 100-300 (30-45 C). The minimum temperature did not fall below 10 C and was generally above 15 C. Rainfall was scattered scantily throughout the sampling period with showers rarely exceeding 1

cm. Maximum relative humidity ranged from 50-100% and tended to be higher during the winter. All crops in Western Arizona are irrigated and irrigation may have exerted greater influence than rain on the microbial communities sampled.

Particle size. Sizes of particles collected by the Burkard cyclone sampler during this study and measured microscopically are summarized in Fig. 7. Particles from 1 μm to 2.5 μm occurred at the greatest frequency. Although observed particle sizes ranged from <1 μm to >30 μm. A few larger particles were occasionally observed, although not in the samples examined microscopically. These larger particles were generally whole insects or insect parts that were entrapped in the sampler. Microscopic examination revealed both organic (spores, plant and animal debris) and inorganic particles (dust, sand). Most propagules of *A. flavus* were within the range expected for conidia (Fig. 8). Few propagules passed through pores of 5 μm or less, but the quantity that passed through 12 μm pores was not significantly different from the control.

Size of ***Aspergillus flavus*** **spores.** Seven-day-old conidia of the applied atoxigenic VCG grown at 31 C on 5/2 agar were spherical and ranged from 3.2 μm to 5.2 μm in diameter. Oven dried conidia were ovoid and crumpled and ranged from 2.4 μm to 5.6 μm x 1.76 μm to 3.6 μm.

Cyclone versus impaction sampler. The number of propagules sampled by impaction onto filters versus by the cyclone sampler is shown in Table 4. Analysis of variance did not indicate differences between the quantity of conidia sampled by the two methods for any of the sampling dates. However, there was great variability among samplings possibly related to the short duration of the sampling period (2 hr).

Rotorod samplers. In lab studies the CMC-glycerol coating was apparently as effective as the silicone grease at entrapping conidia of *A. flavus* (Fig. 9A and B). An analysis of variance showed no difference in the number of conidia sampled using the two coatings, and there was a positive correlation between values for the two coatings for both the quantity of conidia sampled (0.7322, P=0.01) and the frequency of encounters with conidia (0.9501, P=0.001). Cluster sizes of conidia sampled were comparable under both conditions (Fig. 9C). However, viability of conidia sampled in the lab was not quantified. In the field, a time period of exposure test showed

that overloading of the rotorods probably occurred after 2 h sampling (Table 5). In both sampling period tests the 4 h period sampled fewer propagules m^{-3} than the sum of the consecutive 2 h sampling periods. Although propagules of various fungi (*Alternaria, Cladosporium* and *Aspergillus* spp) were consistently sampled, there were few encounters with viable propagules of *A. flavus* at these times. Only *A. niger* was sampled consistently, however, at different sampling times the quantity of viable propagules sampled varied substantially from <1-56 propagules m^{-3}.

Soil, leaf and debris population counts. In 1997 quantities of *A. flavus* on cotton leaves, in soil, and on bolls were compared at the treated site in June and October (Table 6). Analysis of variance indicated differences among substrates in both number of propagules ($F=4.35$, $P=0.006$) and the prevalence of S-strain propagules ($F=676$, $P<0.0001$). Leaf-litter had the most *A. flavus* (2.7×10^5 propagules g^{-3}), and the greatest proportion of S strain (17.3%). Bolls also had large quantities of *A. flavus* propagules (6.9×10^3-1.5×10^4 propagules g^{-3}). In 1998 only soils at the treated and untreated sites were compared (Table 7). The number of soil propagules and the proportions of both the S strain and the applied VCG differed significantly ($P<0.001$, ANOVA) between sites. In June there was a mean of 229 propagules g^{-1} soil at the treated site, but by October there were only 58 propagules g^{-1} of soil. However, at the untreated site propagules per gram shifted from 418 in June to over 1.6×10^4 in October (Table 7). In October the treated site was in lettuce and the untreated site was in cotton (Table 2). In 1997, the S strain was not detected in soil from the treated site and the S strain composed just over 1% of isolates recovered from any substrate at that site. The S strain was more common at the treated site in 1998 with 14% of isolates belonging to the S strain in June compared with 67% at the untreated site. At the treated site in 1997, the applied VCG accounted for 92.7% and 81.3% of the L strain isolates in June and October, respectively. In 1998 the proportion was 81% in June and 66% in October. At the untreated site in 1998 the applied VCG accounted for 43% and 33% of the L strain in June and October, respectively (Table 7).

DISCUSSION

This study describes the dynamics of air-borne microbial propagules in cultivated desert regions of southwestern Arizona. Emphasis is placed on *A. flavus* and influences on the air flora of applications of an atoxigenic *A. flavus* VCG currently used for aflatoxin management in Arizona. Various aspects of the dispersal phase of the epidemiology of *A. flavus* in several crop systems and environments have been investigated (Morrow et al., 1964; Holtmeyer and Wallin, 1980 and 1981; Olanya et al., 1989), and some prior information on aerial dispersal of *A. flavus* in Arizona is available (Lee et al., 1986). However, this is the first time the year-round characteristics of air-borne propagules of *A. flavus* have been described in an agricultural setting during seasons when epidemics of aflatoxin contamination of a crop occurred. In both seasons cottonseed produced throughout this local region experienced aflatoxin contamination at economically damaging levels (Cotty, unpublished data). The severity and distribution of aflatoxin contamination within this area in 1995 and 1996 has been detailed (Bock and Cotty, 1999). The current study shows *A. flavus* is a major component of the air around cotton fields of southwestern Arizona during the summer and autumn periods and it is a common component of air around rotation crops as well. Various other fungi (*Fusarium* spp., *Alternaria* spp. and other *Aspergillus* spp.), and bacteria are also common constituents of the air surrounding agricultural fields in this area.

Aspergillus flavus was counted on a selective medium (MRB) to ensure detection of the maximum number of *A. flavus* propagules. The other fungi (including *A. niger*) did not have this advantage and thus they were undoubtedly undercounted. Indeed, fewer *A. flavus* propagules were detected on either 5/2 or PDA that on MRB. This agrees with a previous report on *A. flavus* isolation using MRB (Cotty, 1994b). There are probably large numbers of fungi that were either uncultivable on the media we employed or were competitively excluded from the culture plates by more aggressive species. We incubated our isolation media at a relatively high temperature (31 C) that may have been inhibitory to many fungal taxa, particularly those that thrive during the winter when our counts of fungi were low.

Lee et al. (1986) previously found large quantities of airborne *A. flavus* propagules associated with cotton production on individual sampling dates in July to September. However, the Lee study had highly variable results, perhaps associated with the brief sampling periods allowed by the Anderson sampler used in that study. In the current study, peaks in total fungal propagules, including *A. flavus* and *A. niger*, occurred between JD 251–321 (September to November). "Shoulder" periods with fewer propagules occurred before and after these dates. The peak periods for catches of all microorganisms were associated with extensive, valley-wide cotton harvest activity and subsequent cultivation associated with stalk-shredding and plow-down (mandated for insect control) and preparation of soils for winter produce crops. Chemical defoliation, harvest, and plow-down create a huge source of organic debris, which support fungal growth. In Arizona, during these periods, temperature maxima frequently exceed 30 C and temperatures remain for most of the day in a range favorable to growth of *A. flavus* (Ashworth et al., 1969; Ayerst, 1969; Marsh et al., 1973; Diener et al., 1987) and similarly adapted fungi. Aflatoxin contamination of cottonseed is particularly common in high temperature regions (Marsh et al., 1973). Sufficient moisture for fungal reproduction, infection, and aflatoxin contamination may be readily available from late season irrigation, rainfall and dew (Bock and Cotty, 1999; Russell et al., 1976).

Cotton is an indeterminate plant and in Arizona where long-season cotton is common, the earliest bolls may mature and open months before the crop is harvested. Large numbers of *A. flavus* propagules were caught during the periods of cotton boll formation, maturation, and harvest. Prevalence of inoculum does not appear to limit cottonseed infection during these periods. Thus, in Arizona, predisposition of the crop is apparently more important than presence of inoculum in dictating which bolls become infected. In the first phase of contamination (during boll development; Cotty, 1997) bolls are typically predisposed by insect damage (Cotty and Lee, 1989). During the second phase (after boll maturation) predisposition occurs when the crop is exposed to warm moist conditions (Ashworth et al., 1969, 1969 and 1971; Diener et al., 1987; Cotty, 1991). The large quantities of conidia in the air observed in the current study

provide constant exposure of open bolls to increasing loads of *A. flavus* propagules. As crops are held in the field later in the season, there are increasing opportunities for crop predisposition to infection by exposure to humidity events during high temperature periods. This may explain the greater aflatoxin content observed in crops harvested later in the season (Bock and Cotty, 1999). Indeed, the large quantities of *A. flavus* observed later in the season support the view that later harvests suffer increased contamination – not just from early infections producing more aflatoxin, but also from new infections (Bock and Cotty, 1999).

The applied atoxigenic VCG belongs to the L strain and is endemic to the test area and ranged from <1% to 4% of *A. flavus* in the soils of this area prior to application in 1996 (Cotty, unpublished data). The treated site appeared to have a significantly greater proportion of the L strain which may be due to competitive exclusion of the S strain by the applied VCG (Cotty, 1994a). We do not have data for previous seasons, but the S strain was more prevalent at the non-treated site than at the treated site, and the proportion of the L strain did not appear to change significantly between 1997 and 1998 suggesting that the effect of treatment did not disappear after a single season. This agrees with previous observations (Cotty, 1999). The relatively high incidence of the applied VCG at the untreated site (up to 47% of the L strain at the untreated site was the applied VCG) probably resulted from dispersal from the site treated in 1996 and 1997 (the distance between the edge of the treated area and the sampler in the non-treated site was about 1 km). Quantities of *A. flavus* propagules sampled at both the treated and untreated sites were similar throughout the 1997 season and thus, application of the atoxigenic VCG apparently altered the composition of *A. flavus* in the air, without altering the total quantity of *A. flavus*. Indeed, air spora from other surrounding areas may well influence the spectrum of spores sampled, and various factors including wind speed and direction and farming activity will affect the propagule type and quantity sampled at a particular time. One advantage of the cyclone sampler is that continuous sampling over 1-week periods is possible, thereby overcoming the effects of transient changes of wind direction or speed which could influence results from samplers operated for short periods.

The most likely source of the relatively high incidence of the applied VCG at the untreated site are the atoxigenic VCG applications. Previous studies (Olanya et al., 1997) have shown linear dispersal gradients of air-borne inoculum of *A. flavus* from waste corn piles in Iowa, with propagules being dispersed at least 14 m. In our study the atoxigenic VCG was applied to a 16 ha block in 1996 and a 65 ha block in 1997, which constitutes a large source of inoculum for aerial dispersal over a period of two years. It is also possible that insects play a role in dispersing the fungus (Olanya et al., 1997). The fact that *A. flavus* is aerially dispersed and can probably travel at least several hundred meters lends support to the use of area-wide applications to establish the atoxigenic VCG and minimize ingress of aflatoxin producing strains from other habitats. This approach would provide the additional benefit to farming communities of reducing contamination of all crops grown in a region. It would also reduce any health risk associated with aflatoxin exposure via respiration (Oyelami et al, 1997; Autrup, et al, 1993) of either conidia containing aflatoxin (Wicklow and Shotwell, 1983), or crop associated dust (Lee et al., 1983; Salim et al, 1998).

Long range movement of *A. flavus* may also be suggested by failure of the air catches to closely mirror the soil composition at either the treated or not-treated sites. High incidences of the S strain were caught at the treated site in 1998 (JD 160 to JD 253) even though soil analyses of the four fields surrounding the sampler indicated a low incidence of the S strain. Either S strain propagules were dispersed to the sampler from beyond the treated area (1 to 1.5 km) or there was preferential dispersal of the S strain from soils during certain periods. Seasonal increases in S strain incidence in soils of western Arizona in July/August have previously been described (Orum et al. 1997). However, the very low levels of S strain isolates in the soils of treated fields suggest compositional differences between cyclone and soil samples reflect movement of both the S strain into the treated area and the applied atoxigenic VCG into the non-treated area. There are diverse crops in this region and propagules may have originated from agricultural fields undergoing soil preparation or harvest. However, it is also possible that S strain propagules originated from native desert areas which greatly outweigh cultivated regions

in the test area and which have significant *A. flavus* communities (Boyd and Cotty, 1998).

We found the S strain was prevalent in the air from May through December (peaking from July to September) which spans the period of boll development and maturation and may be important to the epidemiology of aflatoxin contamination of cottonseed. The S strain produces comparatively greater amounts of aflatoxin than the L strain (Cotty, 1989), and readily infects cotton bolls (Garber and Cotty, 1997). Although the origin of the large proportion of S strain observed in summer and early fall remains unclear, the plume begins before cotton boll maturation and declines during cotton crop harvest. It is thus unlikely, at least initially, to originate from with the current crop. The S strain produces large quantities of sclerotia (Cotty, 1989, Garber and Cotty, 1997) and the plume may reflect release of conidia from sclerotia formed on trash from prior crops. Alternatively the S strain propagules may come from soil disturbance during either harvest of or incorporation of crop debris from alternative crops (i.e. wheat).

The filtration studies suggested that *A. flavus* propagules collected by the cyclone sampler were, for the most part, in the range of conidia (<12 um diameter), rather than larger sclerotia or colonized organic debris. However, air transport of sclerotia from colonized locules (Garber and Cotty, 1999) to the soil must occur and it seems likely some movement of sclerotia between fields occurs. Sclerotia of the S strain are relatively small (S originally designated small sclerotia <400 μm) and dust storms are common in this region. Large quantities of soil and associated organic matter can be driven over vast areas by storms and sclerotia of the S strain would be dispersed.

Both the crop and season greatly influence the magnitude of *A. flavus* soil communities (Orum et al., 1997). In 1997 cotton was produced in a warm season typical of the area. However, spring and early summer of 1998 were uncharacteristically cool in southwest Arizona. This resulted in both the worse cotton crop in memory and reduced conditions favorable to *A. flavus* growth. Significantly less *A. flavus* was sampled at the treated site in 1998. The four-fold reduction in the quantity of *A. flavus* in the soil observed at the treated site between June (wheat

planted) and October (lettuce planted) was probably due to both the cooler year and the change in cropping. Cotton production in Arizona favors development of high densities of *A. flavus* propagules (Orum et al., 1997) and at the non-treated site *A. flavus* propagules in the soil increased under cotton production forty-fold between June and October 1998. However, the quantity of propagules captured by the cyclone sampler at the non-treated site did not differ between 1997 (when cabbage was grown) and 1998. Failure to see an increase in air-borne propagules associated with cotton production is probably attributable to both the cooler year and the reduced amount of cotton immediately adjacent to the non-treated site in 1998 versus 1997. Thus, cotton production outside of the site may have contributed captured propagules to a greater extent in 1997 than in 1998.

To the best of our knowledge this is the first report of a Burkard cyclone sampler being used to sample fungal propagules for studying a plant pathogen. The equipment has many useful aspects that make it practical in a study of plant pathogens, particularly in dry environments. Cyclone samplers can be operated continuously for long periods of time (this equipment ran continuously from May 1997 through March 1999 using solar powered batteries). Operation over long periods prevents wide transient fluctuations in propagule numbers from having a major impact on overall counts. Cyclone samplers collect a dry dust that allows ready quantification of viable propagules through culture on appropriate media. This is particularly useful where size or spore characteristics make identification difficult. The size of conidia (in our study 3.2-5.2 um in diameter) and similarity of spores of *A. flavus* to other *Aspergilli* make it difficult to assess them visually, and counting morphologically distinct colony forming units is a more certain approach. The size ranges of particles sampled in our study also suggest that cyclone samplers would be suitable for sampling many other fungal spores. Numbers of cultivable *A. flavus* propagules caught by the cyclone samplers were comparable to those caught with the filter impaction samplers previously shown to be the most efficient of four air samplers tested for detection of air-borne *A. flavus* spores (Silas, et al, 1986). However, we were unable to sample *A. flavus* propagules in the field using rotorods. Rotorods coated with a carboxy-methyl cellulose based

grease did sample other fungi including *A. niger*. It may be that conidia of *A. flavus*, under field conditions, were rendered non-cultivable by impact on the rotorods. Nonetheless, the rotorods were successful at quantifiably capturing culturable *A. niger* at propagule concentrations similar to those captured by the cyclone sampler.

The formulation currently being used to treat areas of the Mohawk Valley is sterile wheat seed colonized with an atoxigenic *A. flavus* (Bock and Cotty, 1999). Timing of application is an important criterion to maximize the production of conidia while minimizing the risk of product loss to predation or burial. Timing of conidia release from the product is crucial to optimize competitive exclusion of aflatoxin producing strains of *A. flavus* (Cotty and Bayman, 1993). Data presented here suggest *A. flavus* becomes a noticeable component of the air spora by early May. On the basis of this observation, earlier treatments are likely to be more effective, providing temperature and moisture do not limit fungal metabolism and production of conidia. Treatments as early as the first week of May should be considered. At this time other strains of the fungus shall not have had chance to reproduce or colonize substrates and the applied atoxigenic VCG should have increased competitive advantage.

Data presented here suggest that application of an atoxigenic VCG of *A. flavus* at the currently used rate (10 kg colonized wheat seed ha^{-1}) does not significantly increase the overall quantity of *A. flavus* in the air at treated sites as compared to untreated areas. In areas of Arizona where aflatoxin contamination of cottonseed is a perennial problem, *A. flavus* is a major component of the airspora and appears to be dispersed over distances of at least several hundred meters. Early, area-wide application of an atoxigenic VCG would thus make sense for effective aflatoxin control in these intensive agricultural areas in the desert environments of Arizona. Indeed, early application may be necessary to optimize efficacy of applications.

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References

Ashworth, L. J., Jr., McMeans, J. L., and Brown, C. M. 1969. Infection of cotton by *Aspergillus flavus*: Time of infection and the influence of fiber moisture. *Phytopathology* **59**: 383-385.

Ashworth, L. J., Jr., McMeans, J. L., and Brown, C. M. 1969. Infection of cotton by *Aspergillus flavus*: The influence of temperature and aeration. *Phytopathology* **59**: 669-673.

Ashworth, L. J., Jr., Rice, R.E., McMeans, J. L., and Brown, C. M. 1969. The relationships of insects to infection of cotton bolls by *Aspergillus flavus*. *Phytopathology* **61**: 488-493.

Autrup, J.L., Schmidt, J., and Autrup, H. 1993. Exposure to Aflatoxin B1 in animal-feed production plant workers. *Environ. Health Perspectives* 99:195-197.

Ayerst, G. 1969. The effects of moisture and temperature on growth and spore germination in some fungi. *J. of Stored Prod. Res.* **5**: 127-141.

Ballew, H.W. 1997. Selection of a microfiltration membrane for optimum results. *American Laboratory* 29: 8-10.

Bayman, P. and Cotty, P. J. 1991. Vegetative compatability and genetic diversity in the *Aspergillus flavus* population of a single field. *Can. J. Botany* **69**: 1707-1711.

Bock, C.H. and Cotty, P.J. 1999. The relationship of gin date to aflatoxin contamination of cottonseed in Arizona. *Plant Disease* **83**: 279-285.

Bock, C.H. and Cotty, P.J. 1999. Wheat seed colonized with atoxigenic *Aspergillus flavus*: characterization and production of a biopesticide for aflatoxin control. *Biocontrol Sci. Tech.* 9:529-543.

Bothast, , R.J., Beuchat, L.R., Emswiler, B.S., Johnson, M.G. and Pierson, M.D. 1978. Incidence of airborne *Aspergillus flavus* spores in cornfields of five states. *App. and Env. Biol.* **35**: 627-628.

Boyd, M. L., and Cotty, P. J. 1998. Spatiotemporal distribution and density of Aspergillus section flavi propagules in Sonoran desert habitats. (Abstr.) *Phytopathology* **88**(suppl.):S10

Brown, R.L., Cotty, P.J. & Cleveland, T.E. 1991. Reduction in aflatoxin content of maize by atoxigenic strains of *Aspergillus flavus*. *J. of Food Prot.* **54**: 623-626.

Cotty, P.J. 1988. Aflatoxin and sclerotial production by Aspergillus flavus: influence of pH. *Phytopathology* **78**: 1250-1253.

Cotty, P. J. 1989. Virulence and cultural characteristics of two *Aspergillus flavus* strains pathogenic on cotton. *Phytopathology* **79**: 808-814.

Cotty, P.J. 1991. Effect of harvest date on aflatoxin contamination of cottonseed. *Plant Disease* **75**: 312-314.

Cotty, P.J. 1992. Use of native *Aspergillus flavus* strains to prevent aflatoxin contamination. United States Patent 5,171,686, issued Dec. 15, 1992.

Cotty, P. J. 1994a. Influence of field application of an atoxigenic strain of *Aspergillus flavus* on the populations of *A. flavus* infecting cotton bolls and on the aflatoxin content of cottonseed. *Phytopathology* **84**: 1270-1277.

Cotty, P.J. 1994b. Comparison of four media for the isolation of *Aspergillus flavus* group fungi. *Mycopathologia* **125**: 157-162.

Cotty, P.J. 1997. Update on methods to prevent aflatoxin formation. Oil Mill Gazetteer **103**:33-38.

Cotty, P.J. and Bayman, P. 1993. Competitive exclusion of a toxigenic strain *of Aspergillus flavus* by an atoxigenic strain. *Phytopathology* **83**: 1283-1287.

Cotty, P.J. and Garber, R.K. 1997. Formation of sclerotia and aflatoxins in developing cotton bolls infected by the s strain of *Aspergillus flavus* and potential for biocontrol with an atoxigenic strain. *Phytopathology* **87**: 940-945.

Cotty, P.J. and Lee, L.S. 1989. Aflatoxin contamination of cottonseed: Comparison of pink bollworm damaged and undamaged bolls. *Trop. Sci.* **29**:273-277.

Diener, U. L., Cole, R. J., Sanders, T. H., Payne, G.A., Lee, L. S., & Klich, M. A. 1987. Epidemiology of aflatoxin formation by *Aspergillus flavus*. *Ann. Rev.Phytopath.* **25:** 249-270.

Dorner, J. W., Cole, R. J. & Blankenship, P. D. 1992. Use of a biocompetitive agent to control preharvest aflatoxin in drought stressed peanuts. *J. of Food Prot.* **55:** 888-892.

Dorner, J. W., Cole, R. J., and Wicklow, D. T. 1999. Aflatoxin reduction in corn through field application of competitive fungi. *J. Food Protection* **62**: 650, 1999.

Emberlin, J. C. and Babbonian, C. 1995. The development of a new method of sampling airborne particles for immunological analysis. *Proceedings, XVI European Congress of Allergology and Clinical Immunology, Madrid, Spain, 24-25 June 1995.*

Holtmeyer, M.G. and Wallin, J.R. 1980. Identification of aflatoxin producing atmosperic isolates of *Aspergillus flavus*. *Phytopathology* **70**: 325-327.

Holtmeyer, M.G. and Wallin, J.R. 1980. Incidence and distribution of airborne spores of *Aspergillus flavus* in Missouri. *Plant Disease* **65**: 58-60.

Lee, L.S., Koltun, S.P., and Buco, S. 1983. Aflatoxin distribution in fines and meats from decorticated cottonseed. *J. American Oil Chem. Soc.* **60**:1548-1549.

Lee, L.S., Lee, L.V. Jr., and Russell, T. E. 1986. Aflatoxin in Arizona cottonseed: field inoculation of bolls by *Aspergillus flavus* spores in wind-driven soil. *J. American Oil Chem. Soc.* **63**:530-532.

Marsh, P.B., Simpson, M.E., Craig, G.O., Donoso, J. and Ramey, H.H. Jr. 1973. Occurrence of aflatoxins in cottonseed at harvest in relation to location of growth and field temperature. *J. Env. Quality* **2**: 276-281.

Morrow, M.B., Meyer, G.H. and Prince, H.E. 1964. A summary of airborne mold surveys. *Annals of Allergy* **22**: 575-587.

Oyelami, O.A., Maxwell, S.M., Adelusola, K.A., Aladekoma, T.A., and Oyelese, A.O. 1997. Aflatoxins in the lungs of children with kwashiorkor and children with miscellaneous diseases in Nigeria. *J. Toxicology and Environ. Health* **51**:623-628.

Olanya, O.M., Hoyos, G.M., Tiffany, L.H. and McGee, D.C. 1997. Waste corn asa point source of inoculum for *Aspergillus flavus* in the corn agroecosystem. *Plant Disease* **81**:576-581.

Orum, T.V., Bigelow, D.M., Nelson, M.R., Howell, D.R. and Cotty, P.J. 1997. Spatial and temporal patterns of *Aspergillus flavus* strain composition and propagule density in Yuma County, Arizona, soils. *Plant Disease* **81**: 911-916.

Park, D. L., Lee, L. S., Price, R. L. and Pohland, A. E. 1988. Review of the decontamination of aflatoxin by ammoniation: current status and regulation. *J. Assoc. of Off. Ana. Chemists* **71**: 685-703.

Perkins, W.A. 1957. The rotorod sampler. Second Semi-Annual Report, Aerosol Laboratory, Department of Chemistry and Chemical Engineeriung, Stanford, USA: Stanford University, CML 186.

Russell, T. E., Watson, T. F., and Ryan, G. F. 1976. Field accumulation of aflatoxin in cottonseed as influenced by irrigation termination dates and pink bollworm infestation. *Appl. Env. Micro.* **31**: 711-713.

Salim, M. I., Juchems, A. M., and Popendorf, W. 1998. Assessing airborne aflatoxin B1 during on-farm grain handling activities. *Am. Industrial Hygiene Asst. Journal* **59**:252-256.

Silas, J.C., Harrison, M.A., Carpenter, J.A., and Floyd, J.B. 1986. Comparison of particulate air samplers for detection of airborne *Aspergillus flavus* spores. *J. Food Protection* **49**:236-238.

Wicklow, D.T. and Cole, R.J. 1982. Tremorgenic indole metabolites and aflatoxins in sclerotia of *Aspergillus flavus*: and evolutionary perspective. *Can. J. of Botany* **60**: 525-528.

Wicklow, D.T., and Shotwell, O.L. 1983. Intrafungal distribution of aflatoxins among conidia and sclerotia of Aspergillus flavus and Aspergillus parasiticus. *Can. J. Microbiol.* **29**:1-5.

1 TABLE 1. Colony forming units (CFU) of *Aspergillus flavus* cultured on different isolation
2 media from samples collected by a cyclone sampler

Field treatment	Media[a]	Mean (CFU/m^{-3})[b]	T-test comparisons	
			Media	t-value, df, P-value
Treated	PDA	17.5	PDA vs 5/2	-0.88, 99, 0.19
	5/2	24.1	5/2 vs MRB	0.73, 109, 0.23
	MRB	32.5	MRB vs PDA	1.45, 80, 0.08
Untreated	PDA	15.7	PDA vs 5/2	-0.18, 119, 0.43
	5/2	16.7	5/2 vs MRB	1.53, 94, 0.06
	MRB	33.0	MRB vs PDA	1.70, 84, 0.05

3
4 [a]media as described in the Materials and Methods.
5 [b]mean CFU/m^{-3} from weekly enumeration of propagule counts in air sampled May 1997 through
6 March 1999 as described in the Materials and Methods.

TABLE 2. Cropping history[a] of the fields adjacent to the Burkard cyclone sampler at the treated and untreated sites in the Mohawk Valley, Arizona

	1997												1998								1999		
Field	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M
Treated	ct	ct	ct	ct	ct	ct	fw	wt	wt	wt	wt	wt	wt	wt	fw	lc	lc	lc	lc	wt	wt	wt	wt
Not-treated	ba	fw	fw	ca	ca	ca	ca	ca	ca	fw	ct	ct	ct	ct	ct	ct	ct	ct	fw	wt	wt	wt	wt

[a]ct = cotton, ca = cabbage, lc=lettuce, fw=fallow, soil preparation for next crop, wh=wheat, ba=barley.

1 TABLE 3. The dimensions of fresh and dried conidia of *Aspergillus flavus*

Treatment	Length (μm)			Width (μm)		
	Mean (st dev)	Max	Min	Mean (st dev)	Max	Min
Fresh	4.22 (0.46)	5.2	3.2	--[a]	--	--
Dried[b]	3.33 (0.42)	5.6	2.4	2.92 (0.42)	3.6	1.76

2

3 [a]fresh conidia are spherical.

4 [b]measured after drying in an oven at 50 C.

TABLE 4. The quantity of *Aspergillus flavus* propagules in the air sampled either by impaction onto membranes or by a Burkard cyclone sampler in the Mohawk Valley, Arizona, 1998

Test	Date	Propagules sampled m^{-3}	
		Cyclone	Impaction
1	June 17	51[a]	29
2	November 18	103	583
3	November 19	389	98
Three Test Mean		181	236

[a]for each date cyclone values do not differ significantly from impaction values by analysis of variance. Values are means of three replicates. Cyclone replicates are single measurements; each impaction replicate is the mean of three measurements taken simultaneously.

TABLE 5. The numbers of fungal propagules (total fungi and *Aspergillus niger*) sampled by the rotorod samplers in the Mohawk Valley, Arizona, 1998

			Total fungi	*A. niger*
Date	Duration of sampling (h)	Rotorod sampler no.	Propagules/m^3 (stdev)[b]	Propagules/m^3 (stdev)[b]
18/11/98	2	1	11.8 (1.5)	-[a]
	2	2	46.0 (26.5)	-
	4	3	28.0 (7.7)	-
18/11/98	2	1	3.1 (1.5)	-
	2	2	3.9 (0.4)	-
	4	3	2.7 (1.9)	-
18/11/98	2	1	8.5 (2.4)	-
	2	2	9.8 (3.0)	-
19/11/98	2	1	11.8 (6.0)	3.4 (3.0)
	2	2	9.1 (0.9)	2.5 (1.9)
19/11/98	2	1	24.3 (0.7)	15.0 (5.5)
	2	2	10.1 (5.2)	5.7 (4.7)
19/11/98	2	1	56.2 (25.2)	4.2 (2.4)
	2	2	50.3 (25.8)	0.5 (0.4)

[a]data not taken.

[b]mean based on three rotorod samplings with two rods each.

TABLE 6. *Aspergillus flavus* communities in the soil and on crop parts in fields treated with an atoxigenic strain of *A. flavus* and adjacent to a Burkard cyclone air sampler in 1997

Month	Substrate	Propagules g^{-1}	S strain (%)	Applied strain (%)[d]
June[a]	Soil	27,916 b[c]	0 l	92.7 z
	Leaves[b]	5,748 b	0 l	100 z
	Bolls	6,944 b	0 l	100 z
October	Soil	34,474 b	0 l	81.3 z
	Leaves	272,461 a	17.3 m	79.3 z
	Bolls	15,124 b	0 l	100 z
	LSD (0.05)	218,972	1.2	25.3

[a]material was sampled in late June, treatment was made in early June.

[b]leaf material was fresh leaves for the late June sample, and leaf litter resulting from chemical defoliation in October.

[c]different letters denote significantly different means (P=0.05). Means separation performed using Tukey's HSD test.

[d]percent of L strain isolates assigned to the applied VCG by vegetative compatibility analysis.

TABLE 7. Quantity of *Aspergillus flavus* in soils of fields surrounding two Burkard cyclone air samplers in 1998 and the incidence of both the S strain of *A. flavus* and an atoxigenic VCG of *A. flavus* applied in to the treated field in 1997

		Propagules[a] g^{-3}				S strain (%)[b]				Applied VCG (%)[c]			
Month	Location[d]	Treated Site		Not-Treated Site		Treated Site		Not-Treated Site		Treated Site		Not-Treated Site	
June	NE	491	b	1,528	b	12	nop	63	lmno	87	wx	40	wxyz
	SE	136	b	86	b	0	p	71	lm	71	wxyz	0	z
	NW	208	b	23	b	29	mnop	90	a	100	w	0	z
	SW	80	b	36	b	13	nop	44	lmnop	66	wxyz	10	yz
	Mean	229		418		14		67		81		43	
October	NE	86	b	198	b	8	op	60	lmno	66	wxyz	50	wxyz
	SE	8	b	17	b	20	mnop	29	mnop	76	wxy	20	xyz
	NW	130	b	18,461	b	17	mnop	68	lmn	65	wxyz	30	[illegible]z
	SW	8	b	47,120	a	3	p	90	l	55	wxyz	30	[illegible]
	Mean	58		16,449		12		62		66		33	
	LSD (0.05)			21,928				55.5				72.9	

[a]location of field sampled in relation to the Burkard cyclone sampler at that site.

[b]percent of *A. flavus* isolates assigned to the S strain by morphological criteria. All *A. flavus* isolates were assigned to either the S or L strains (Cotty, 1989).

[c]percent of L strain isolates assigned to the applied VCG by vegetative compatibility analysis.

[d]different letters denote significantly different means (P=0.05). Means separation performed using Tukey's HSD test.

Fig. 1. The Burkard cyclone sampler (Burkard Manufacturing Co., Rickmansworth, UK) used in this study.

Fig. 2. The location of the two Burkard cyclone samplers in relation to fields treated with the atoxigenic VCG of *Aspergillus flavus* in the Mohawk Valley, Arizona.

Fig. 3. The rotorod sampling apparatus developed for this study showing the construction of tubular PVC piping with motors inserted in joint fittings.

Fig. 4. Characteristics of samples collected by Burkard cyclone samplers at a site treated with an atoxigenic strain of *Aspergillus flavus* and at an untreated site: (A) weight of sampled material; (B) quantity of total fungi, *A. flavus,* and *A. niger*; (C) proportion of total fungi consisting of *A. flavus*; (D) proportion of *A. flavus* in relation to *A. niger*; and (E) quantity of bacteria. *indicates missing data points.

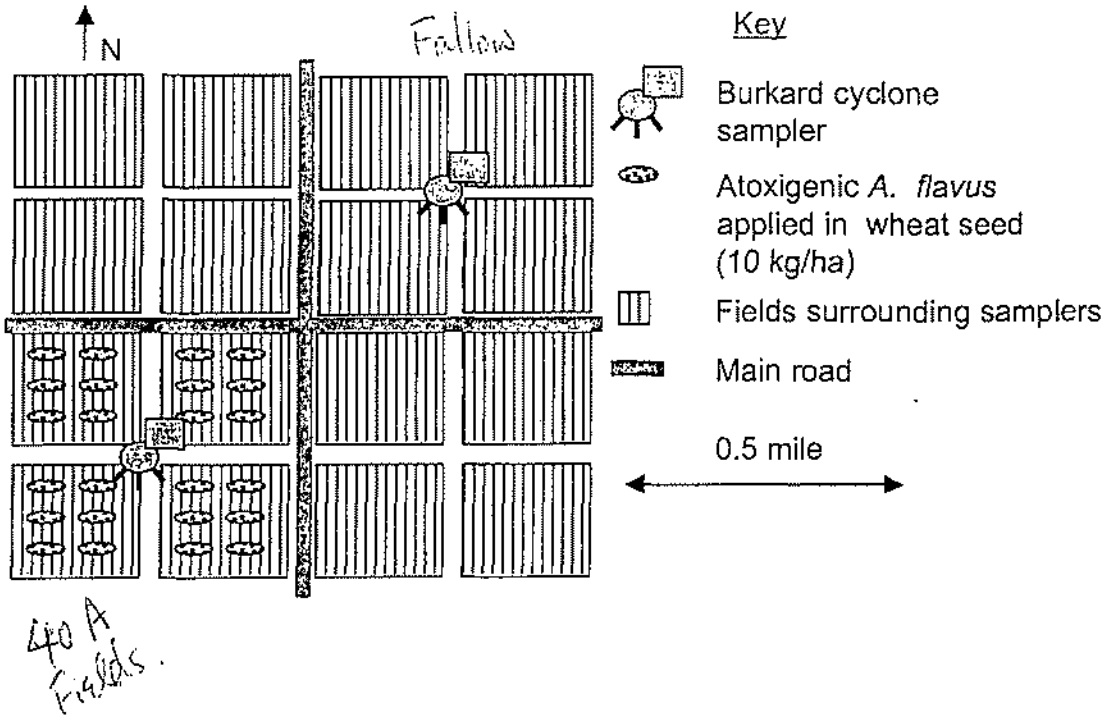
Fig. 5. Characteristics of *A. flavus* communities sampled by Burkard cyclone samplers at a site treated with an atoxigenic vegetative compatibility group (VCG) and at an untreated site: (A) proportion of *A. flavus* consisting of the L and S strains; (B) proportion of the L strain consisting of the applied atoxigenic VCG. * indicates missing data points.

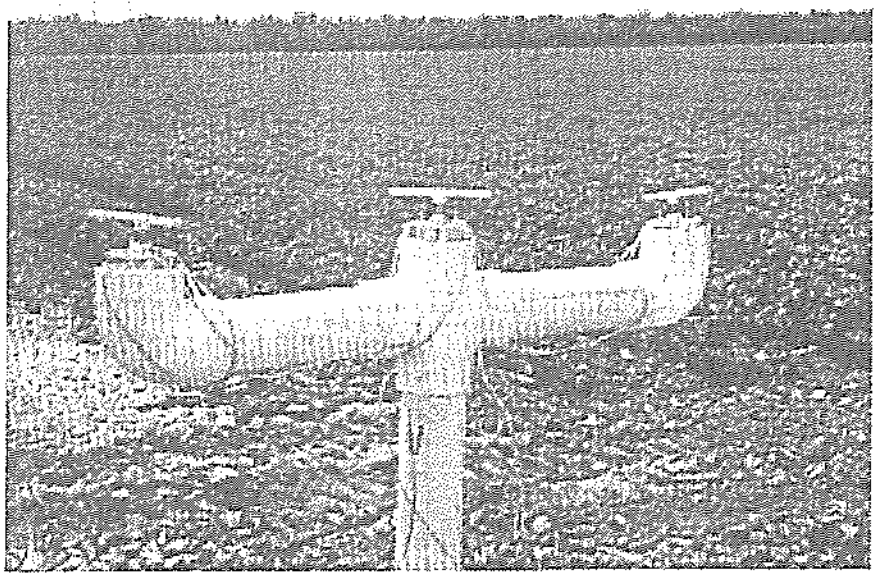
Fig. 6. Weather data for Roll, AZ, from 1997-1999.

Fig. 7. Frequency of different size particles sampled by the Burkard cyclone sampler.

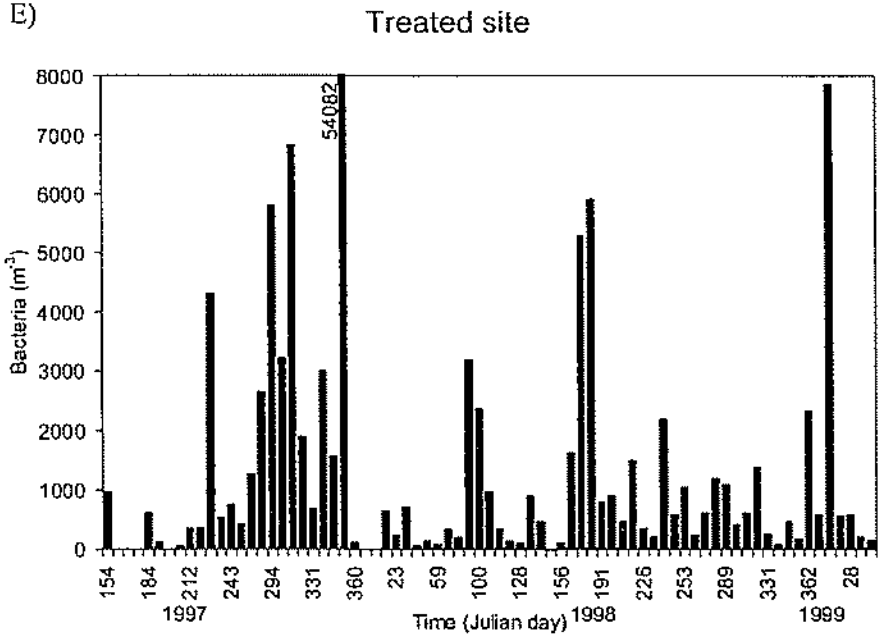
Fig. 8. Passage of *Aspergillus flavus* propagules sampled by the Burkard cyclone sampler through membrane filters with different pore sizes.

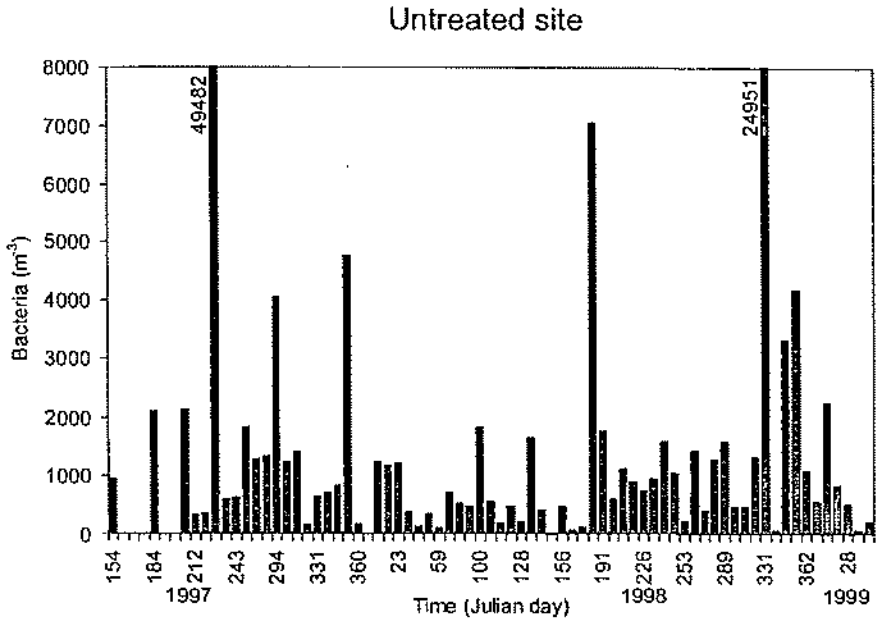
Fig. 9. The results of laboratory tests using rotorods coated with either silicone grease or carboxymethylcellulose/water/glycerol to sample conidia of *Aspergillus flavus* (A) numbers of conidia sampled, (B) the frequency of encounters with conidia, and (C) the range of cluster sizes of conidia sampled.


N
Fallow
Key
Burkard cyclone sampler
Atoxigenic *A. flavus* applied in wheat seed (10 kg/ha)
Fields surrounding samplers
Main road
0.5 mile
40 A Fields.

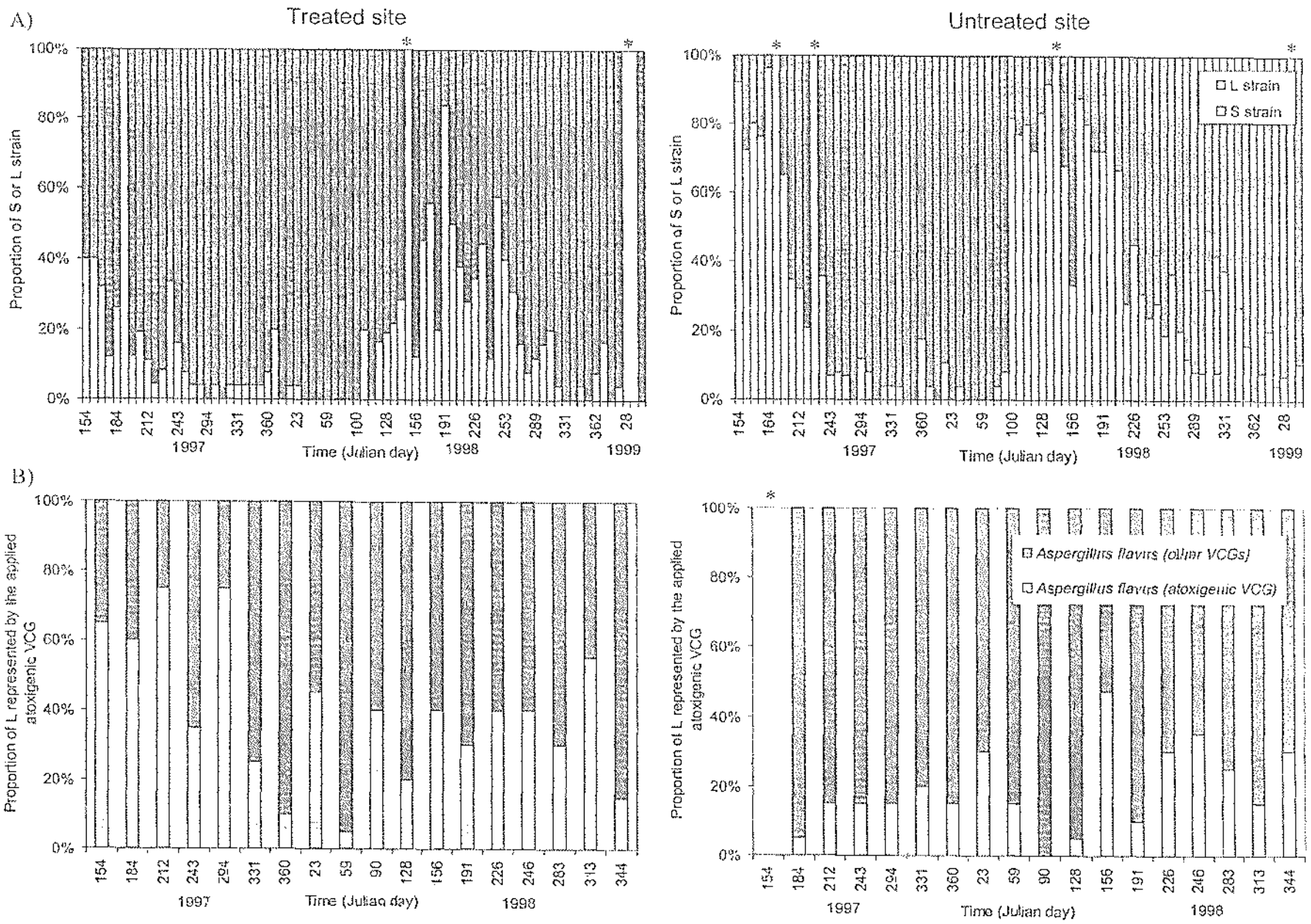


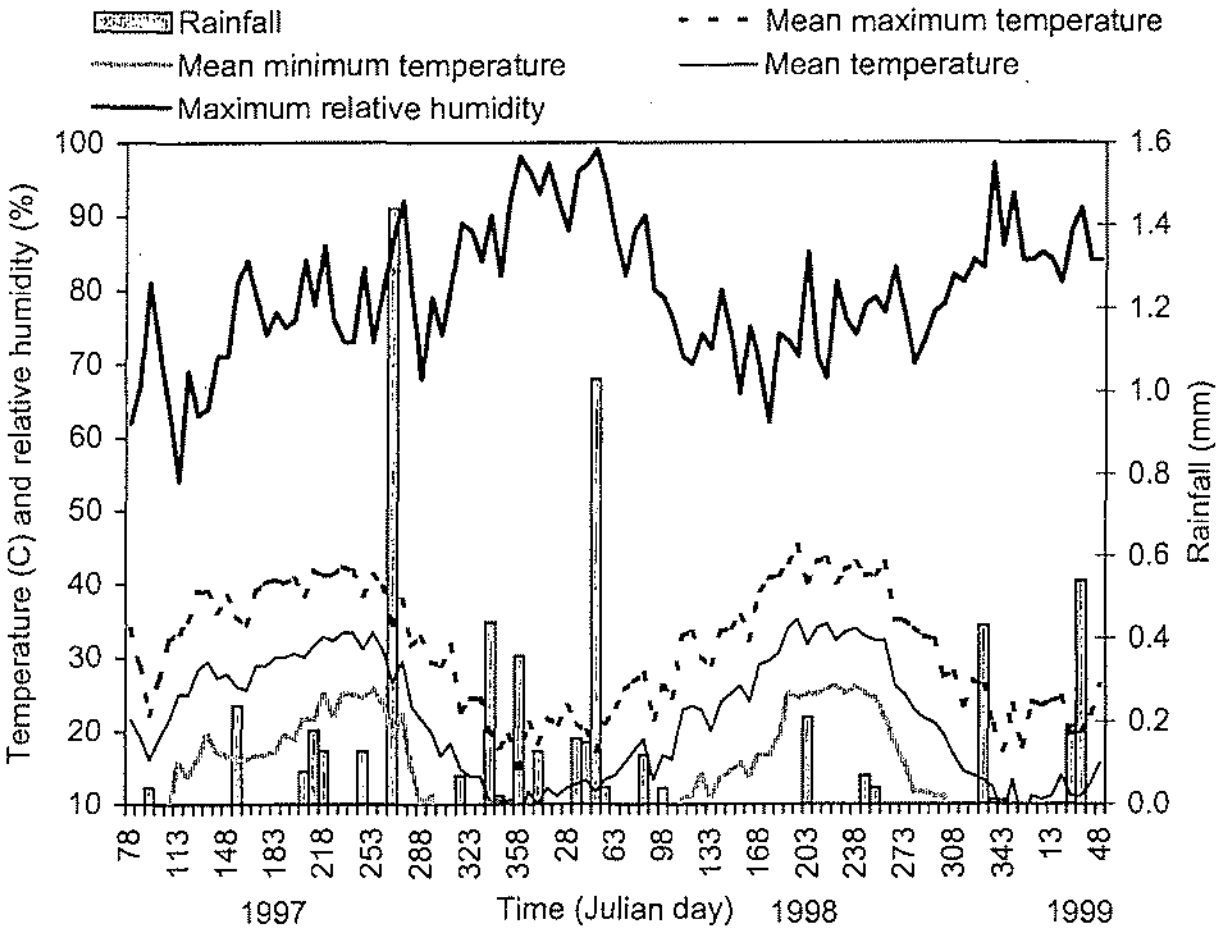
E)

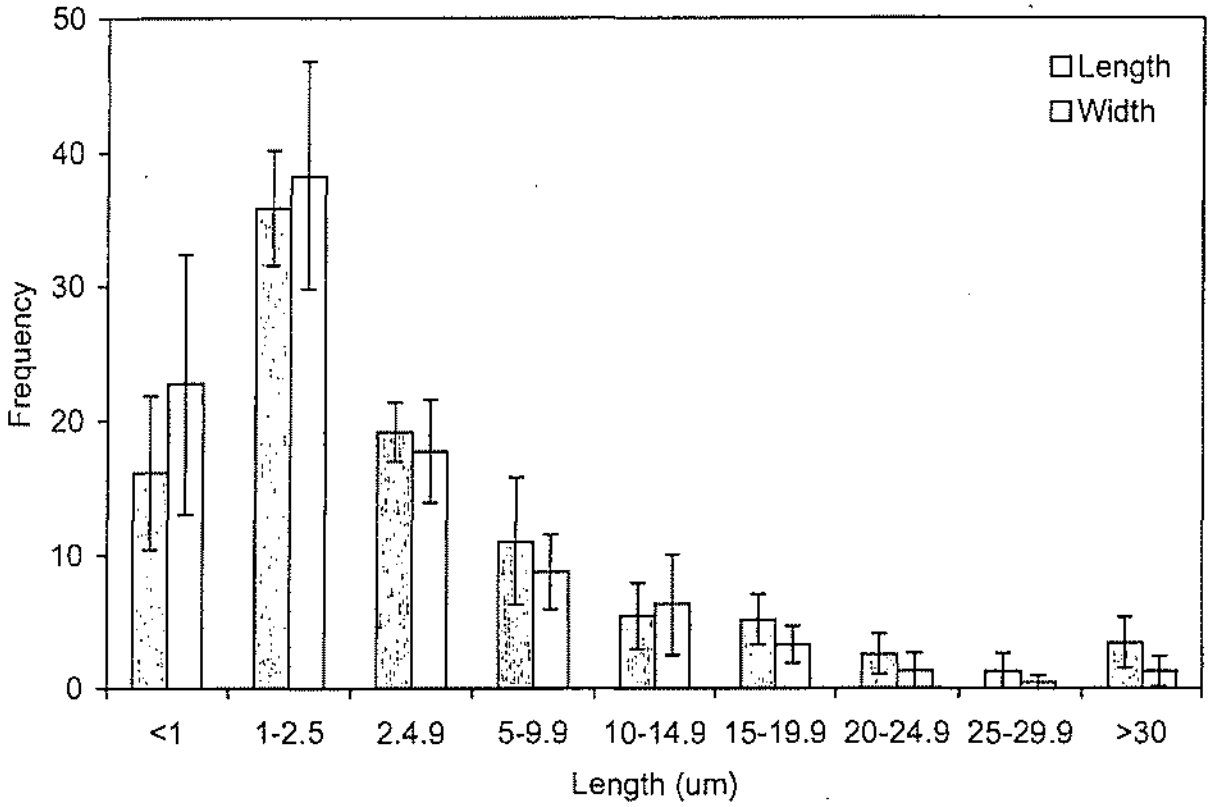

Treated site
Bacteria (m-3)
8000
7000
6000
5000
4000
3000
2000
1000
0
54082
154
184
212
243
294
331
360
23
59
100
128
156
191
226
253
289
331
362
28
1997
1998
1999
Time (Julian day)

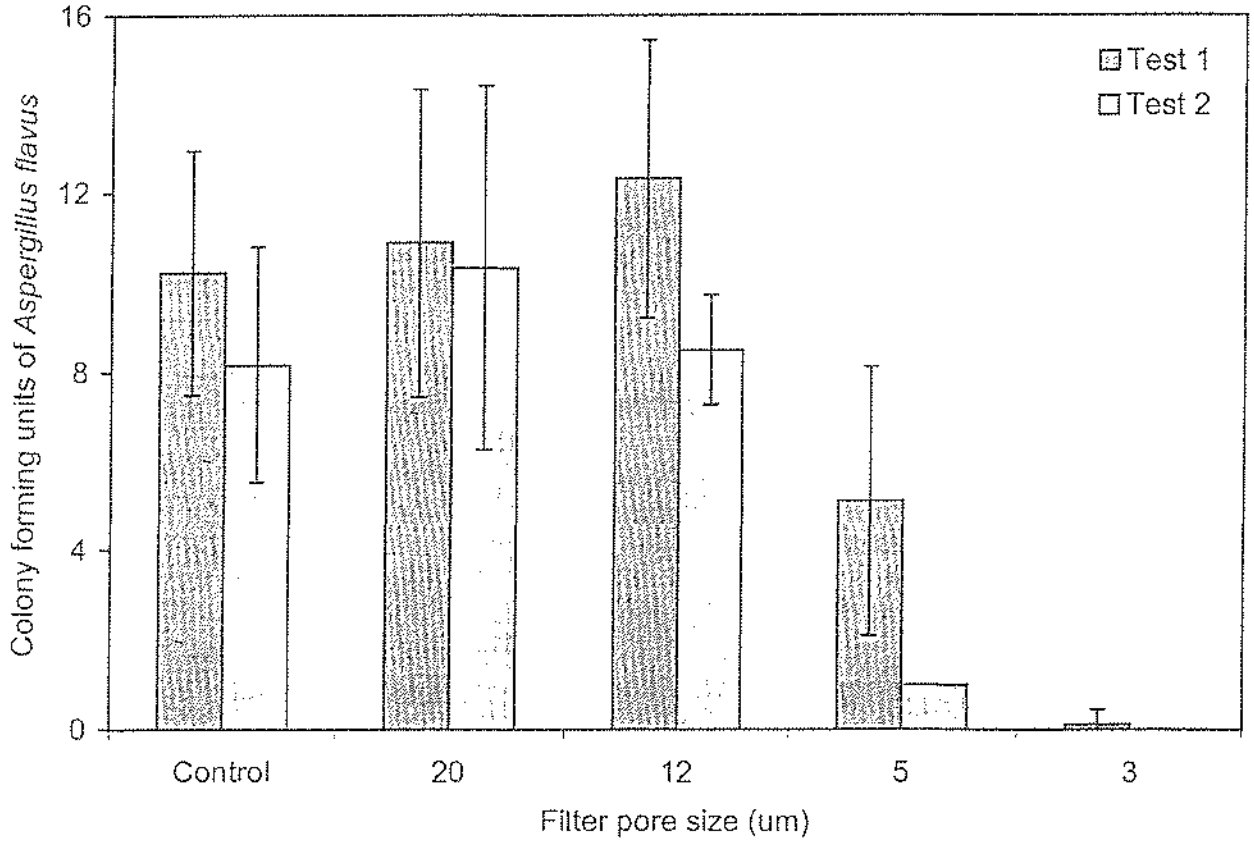

Untreated site
Bacteria (m-3)
8000
7000
6000
5000
4000
3000
2000
1000
0
49482
24951
154
184
212
243
294
331
360
23
59
100
128
156
191
226
253
289
331
362
28
1997
1998
1999
Time (Julian day)

Epidemiology of *Aspergillus flavus* in Arizona, Figure5

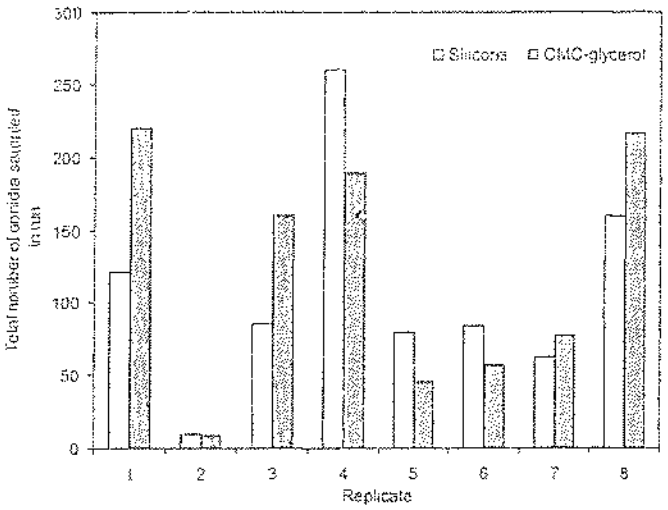



Rainfall
Mean minimum temperature
Maximum relative humidity
Mean maximum temperature
Mean temperature
Temperature (C) and relative humidity (%)
Rainfall (mm)
100
90
80
70
60
50
40
30
20
10
1.6
1.4
1.2
1.0
0.8
0.6
0.4
0.2
0.0
78
113
148
183
218
253
288
323
358
28
63
98
133
168
203
238
273
308
343
13
48
1997
Time (Julian day)
1998
1999

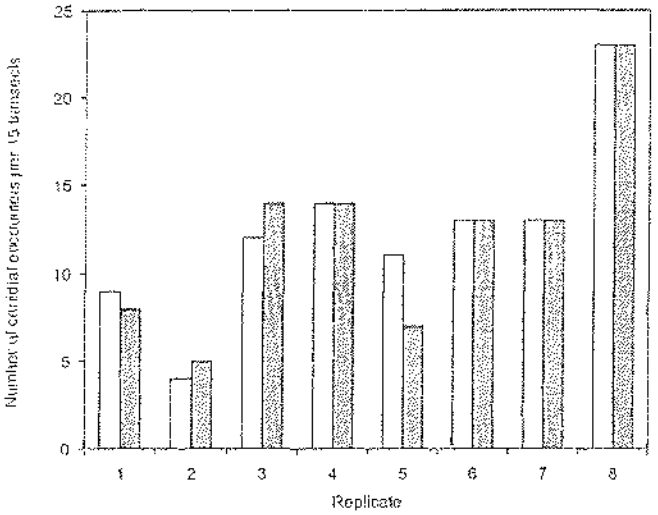

50
40
30
20
10
0
Frequency
Length
Width
<1
1-2.5
2.4.9
5-9.9
10-14.9
15-19.9
20-24.9
25-29.9
>30
Length (um)


16
12
8
4
0
Colony forming units of Aspergillus flavus
Test 1
Test 2
Control
20
12
5
3
Filter pore size (um)

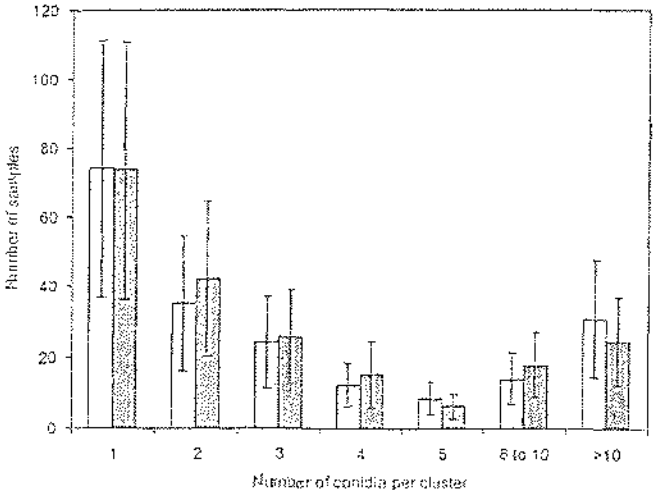
(A)


Silicone
CMC-glycerol
Total number of conidia sampled in mm
Replicate

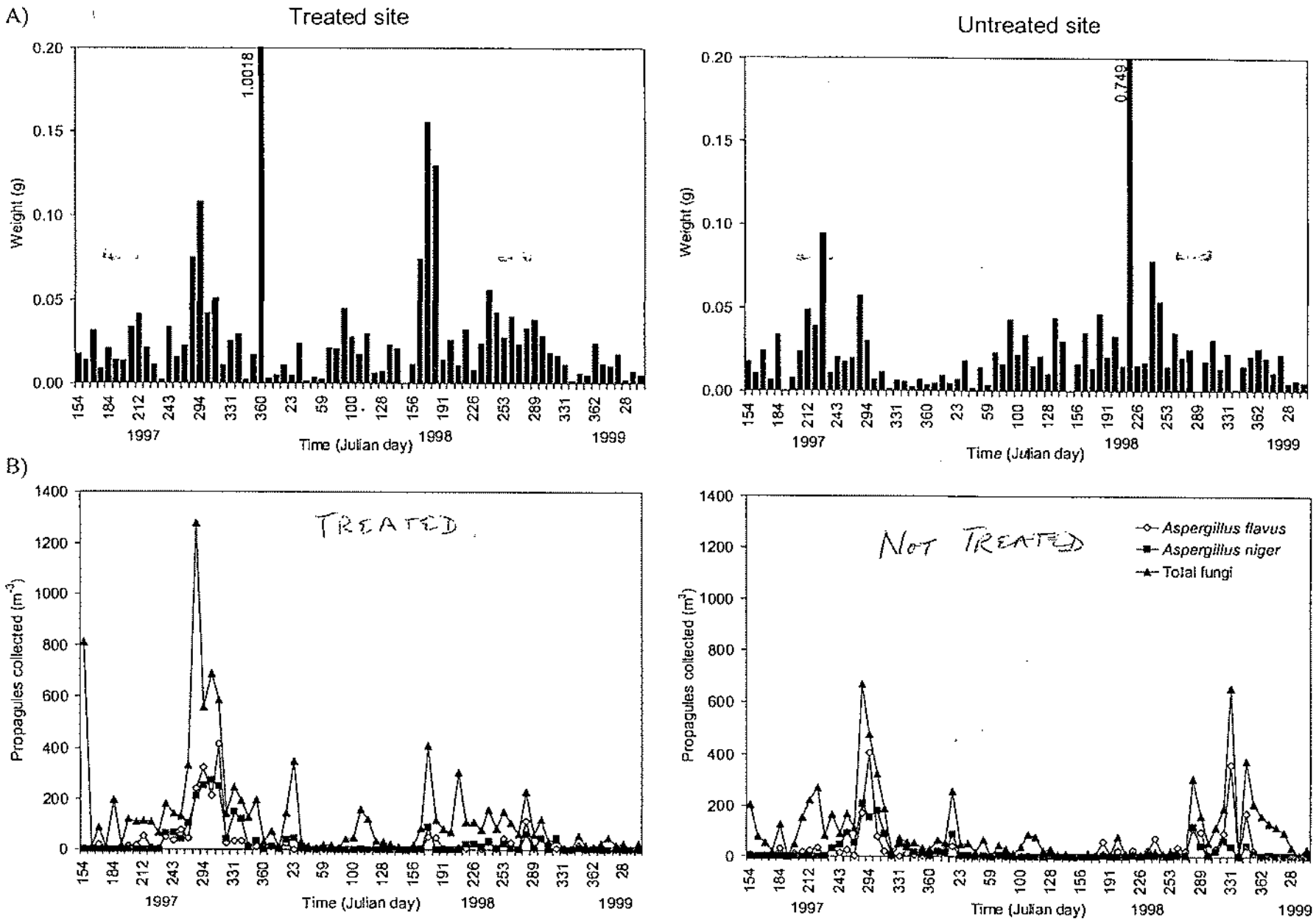
(B)


Number of conidial encounters per 15 transects
Replicate

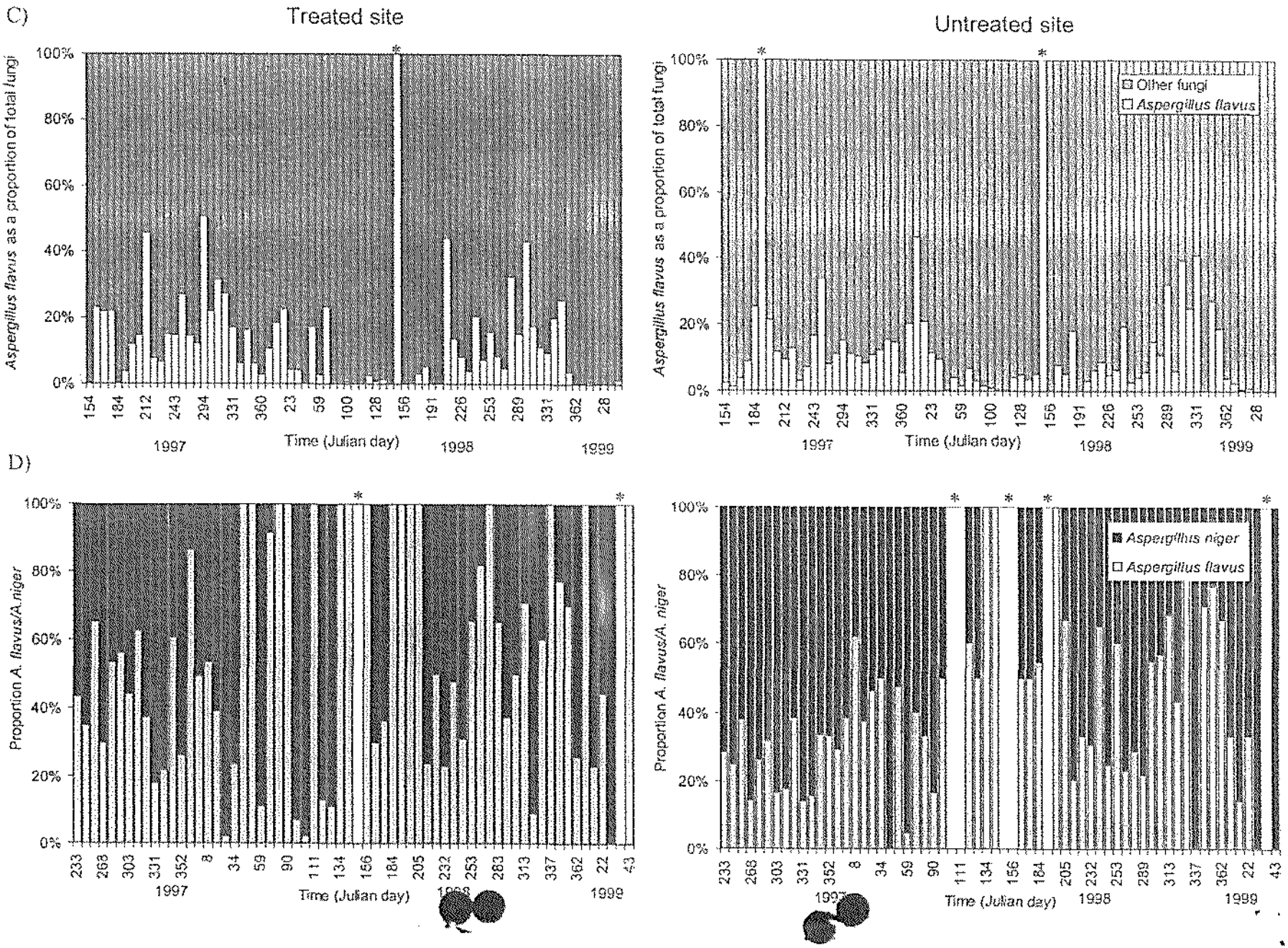
(C)


Number of samples
Number of conidia per cluster

Epidemiology of *Aspergillus flavus* in Arizona, Figure 4



Epidemiology of *Aspergillus flavus* in Arizona, Figure 4, cont.



AGENDA

EPA PREREGISTRATION MEETING

MICROBIAL PRODUCT: ASPERGILLUS FLAVUS AF36 ON COTTON IN ARIZONA

Tuesday June 27, 2000 at ~~10:30 AM~~ 1:00 PM WJBiehn
Room 912
EPA Crystal Mall #2
1921 Jefferson Davis Highway, Arlington, VA

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   Dr. Phillip J. Wakelyn

2. Airborne spore counts of Aspergillus flavus in treated and untreated fields
   Dr. Peter Cotty

3. Aspergillus flavus in Natural Habitats
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4. Toxicity testing and other data needed for registration
   a) Acute Pulmonary Toxicity/Pathogenicity Requirement in Mammals
   b) Avian Acute Oral Toxicity/Pathogenicity Requirement
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   d) Honey Bee Testing Requirement

5. Other items
   a) Options for use and testing of AF36 in the year 2001 in Arizona
   b) Discussion

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DEC 14 1999

Thanks, Stan!

Denise
6/23/00

Dr. Bill Biehn
Technology Center of New Jersey
681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390

Dear Dr. Biehn:

Subject: *Aspergillus flavus* AF36 on cotton in Arizona
Experimental Use Permit Yearly Report
Proposed Section 3 Registration

Below are the data required (a) in the yearly report of the extended Experimental Use Permit (EUP) and (b) a description of data required for the Section 3 registration for *Aspergillus flavus* AF36 on cotton in Arizona. These requirements are summarized in bold and a brief discussion of the rationale behind each of the data requirements follows each requirement.

I. Extended EUP Yearly Report

A. Health effects

1. DATA REQUIRED for Quality Assurance - The yearly report for the EUP must include a summary of the analyses for each batch , showing levels of (a) aflatoxin and (b) human pathogen and other contaminant(s) in the batches and notations of the batches destroyed. During the EUP extension, details of the laboratory tests supporting these summarized data reports must be kept in your records and are subject to audit.

Quality Controls (product identity and aflatoxin production): In the yearly report for the EUP, provide summaries of records to demonstrate that:

(a) The fungus present on the wheat seeds is AF36. This identification can be done by vegetative compatibility.

(b) *A. flavus* AF36 has not acquired the ability to produce aflatoxins (i.e., test for aflatoxins). You must include in your records notation of *A. flavus* AF36 batches which were destroyed because of any significant level of aflatoxin produced by that batch. Details of these batch analyses must be maintained in your laboratory or production records and are subject to audit.

Quality Controls (human pathogens and other microbial contaminants): Quality control measures must be identified, reported to the Agency, and implemented to indicate what levels of contaminants are

considered acceptable. This includes human pathogens, as well as other contaminating microbes. Batches of the pesticide containing contaminants above regulatory levels, must be destroyed.

B. Ecological Effects

For a detailed discussion of the ecological data requirements below, see the attached DERs by Dr. Doug Gurian-Sherman. If discussion about the protocols or any other further clarification about field monitoring is needed, feel free to consult with us.

1. DATA REQUIRED - air monitoring of spores: Data for each of two seasons must be included in the annual report of the EUP and submitted in support of the proposed Section 3 registration.

During the EUP, **air monitoring of spores** is required to determine whether total *A. flavus* spore production in treated cotton fields is significantly higher than in untreated fields. Data presented in Volume 1 of the study, completed 12/8/98, suggest that *A. flavus* inoculum production in treated fields is typically not higher than in untreated agricultural fields. However, the studies presented were not designed to determine whether this is true, and therefore air sampling studies of *A. flavus* conidia in treated and untreated fields are required. Reports must include data from July through October of each season. If the genetic marker test is available (see DATA REQUIREMENT 2 for human health effects below) provide data to demonstrate the relative proportions of AF36 to total *A. flavus*. These data are required because pulmonary exposure is an important route for avian aspergillosis infection.

2. DATA REQUIRED - Propagules in cotton field soil: Collect data to determine the amount of *A. flavus* propagules in cotton field soil and on the crop at maturity.

Data presented to demonstrate the lack of change in the amount of propagules in cotton field soil one year following treatment, and on the crop at maturity, were sufficient to support the proposed expanded EUP. However, these reports demonstrated a high level of variability. Because this risk assessment relies substantially on exposure data and AF36 is a possible pathogen, the Agency requires analyses of these soil samples, at least for an additional year, to support your application for full Section 3 registration.

II. SECTION 3 REGISTRATION DATA REQUIREMENTS

The following data are required for the Section 3 registration. Some of these requirements are described in detail above under the EUP since they are routine analyses required for record-keeping.

A. Health Effects

1. DATA REQUIRED - During production you must submit summaries of the Quality Assurance reports of all production batches for (a) aflatoxin and (b) human pathogen contaminants and other contaminants and metabolites of toxicological concern. Your report must include notations of the batches of *A. flavus* AF 36 destroyed on the basis of aflatoxin or any other contamination above regulatory levels.

Quality Control: To ensure that production batches are consistent, you must continue to monitor them as required above for the EUP extension. Provided that the manufacturing process remains unchanged, and the production batches meet Agency requirements, frequency of the testing may decrease. The requirement will always remain to destroy batches (lots) containing contaminants of

toxicological concern. Such contaminants include either aflatoxin producing *A. flavus*, or aflatoxin itself, or other human pathogens or microbial contaminants or any other potentially toxic metabolites. Only summaries of these tests must be submitted to the Agency. Details of these data must be available for laboratory audits or other enforcement actions as required under the regulations. If the manufacturing method changes from that used for the EUP, you must submit appropriate product identity, product chemistry, and quality control/assurance data to support the new manufacturing method..

2. DATA REQUIRED - A genetic marker test or other more definitive Quality Assurance procedure is required to distinguish *A. flavus* AF 36 from other *A. flavus* species.

An attempt must be made to develop another tool/mechanism, rather than plus/minus vegetative compatibility to differentiate *Aspergillus flavus* AF36 from other *A. flavus* species. Such a test may be a genetic marker or another mechanism sensitive enough to differentiate and enumerate the population of AF 36 in cotton field samples. In other words, the detection limit should provide adequate assurance that the population of AF 36, versus other *A. flavus* strains can routinely and accurately be determined. For additional information regarding this requirement see Agency memorandum dated May t4, t999 from Michael T. Watson to Shanaz Bacchus.

3. DATA REQUIRED - Acute pulmonary toxicity/pathogenicity study in appropriate mammalian model.

Acute pulmonary toxicity/pathogenicity in mammals: Because no data have been submitted for the EUP to demonstrate the acute pulmonary toxicity/pathogenicity of *A. flavus* AF36 to mammals, guideline studies conducted in an appropriate mammalian model are required for a Section 3 registration.

B. Ecological Effects

In addition to the air and soil monitoring of spores discussed above, the Agency requires the following ecological effects data to support the Section 3 registration. It is recommended that you use two different species of birds for the avian acute oral and acute pulmonary studies (1 and 2 below). These two data requirements can be discussed with Agency scientists at a teleconference, if necessary.

1. DATA REQUIRED - Based on the observations below, an acute avian oral toxicity/pathogenicity study is required in order to determine the ecological effects of AF36 on avian species to satisfy guideline requirements. These data will be required for the Section 3 registration.

Acute oral toxicity/pathogenicity to birds. Bird census data (MRID 444642-02), submitted in support of the permit, suggest that native bird species are present in cotton fields in Arizona during and after pesticide application. Both studies which present census data (MRID 444642-02 and 444526-15) conclude that red wing blackbirds are the predominant species in cotton fields. However, MRID 444642-02, Table V, demonstrates that many other species are present in cotton fields at frequencies (~t5 - 100%) comparable to adjacent native habitat. In addition, MRID 444642-02 reported that a significant proportion of birds were foraging in the fields. MRID 444526-15 demonstrated much lower percentage of foraging, but suggested that this was due to experimental difficulties and that actual percentages were likely to be much higher. MRID 444779-01 has also been reviewed, but the extensive census data of the other two studies are more relevant to risk assessment of the current biopesticide. Therefore, even if the amount of treated wheat applied (t0 lb/A) would not be enough to attract birds to cotton fields, birds are present in any case and are likely to find some of the seed. Consequently, an acute avian oral toxicity/pathogenicity study is required.

2. DATA REQUIRED - Avian acute pulmonary toxicity/pathogenicity study in the northern bobwhite quail.

Avian Acute Pulmonary Pathogenicity: *A. flavus* is a known pathogen of birds. Because birds are expected to be present in cotton fields after sporulation of AF36, there is a potential for pulmonary exposure to avian species. An avian acute pulmonary toxicity/pathogenicity study in the northern bobwhite quail is required to ascertain the effects of *A. flavus* AF36 on birds.

3. DATA REQUIRED - Non-target study to demonstrate effects on honey bee.

Non-target bee data: The published literature indicates that several bee species are pollinators of cotton, and may be present in cotton fields at flowering, when AF36 treated wheat would be present. *A. flavus* is known to cause stone brood of honey bees, and therefore hive exposure studies are required. Since preliminary data, discussed above, suggests that exposure is probably not higher for bees in treated than untreated fields, these studies may be performed during the EUP and submitted in support of the Section 3 registration.

The data discussed above must be submitted in the yearly report of the EUP and/or in support of the Section 3 registration as indicated in this letter. A summary of the time frame for the submission of the data is provided in the Attachment (1 page). The proposed time frame indicates that potential Section 3 registration depends on the acceptability of the EUP data. If you have any further questions, do not hesitate to call Shanaz Bacchus at 703-308-8097.

Sincerely,

Janet L. Andersen, Ph.D.
Director
Biopesticides and Pollution
Prevention Division.

cc: Larry Attila
J. Maguire

Summary of data requirements for the EUP yearly report and the proposed Section 3 registration for *A. flavus* AF36 on cotton in Arizona

Data requirements for the EUP yearly report		
Guideline	**Data required**	**Required by**
151-20 through 151-25	Summary analyses of each batch, product identity, levels of aflatoxin and other contaminant analyses	Jan 2000 Nov/Dec 2000
Case by case: Similar to 40 CFR 158.640: Gdln. 93-16	Product performance, Efficacy testing of fungicide, product for control of organisms producing mycotoxins - air and soil monitoring of *A. flavus* spores	Jan 2000 Nov/Dec 2000
Data requirements for Section 3 registration		
Guideline	**Data required**	**Required by**
	Data from EUP yearly report above	Nov/Dec 2000
151-20 through 151-25	Genetic marker test for identification of *A. flavus* AF36; Summary analyses of each batch, product identity, levels of aflatoxin and other contaminant analyses	March 2000 Nov/Dec 2000
154-16	Avian acute oral toxicity/pathogenicity	Nov/Dec 2000
154-17	Avian acute pulmonary toxicity/pathogenicity	Nov/Dec 2000
154-24	Honey bee testing	Nov/Dec 2000

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EPA United States Environmental Protection Agency

Federal Register Document

Related Material

- Other Related Documents

[Federal Register: May 26, 1999 (Volume 64, Number 101)]
[Rules and Regulations]
[Page 28371-28374]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr26my99-10]

[[Page 28371]]

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300860; FRL-6081-2]
RIN 2070-AB78

Aspergillus flavus AF36; Pesticide Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the biological Aspergillus flavus AF36, a non-aflatoxin producing strain of A. flavus, on cotton when applied/used as an antifungal agent. The Interregional Research Project Number 4 (IR-4) submitted an amended Pesticide Petition (PP) 5E4575 to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), and also to comply with the Food Quality Protection Act of 1996 (FQPA) requesting an extension of the temporary exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of Aspergillus flavus AF36. The temporary exemption from the requirement of a tolerance will expire on December 30, 2000.

DATES: This regulation is effective May 26, 1999. Objections and requests for hearings must be received by EPA on or before July 26, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300860], must be submitted to: Hearing Clerk (1900], Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ``Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O.

Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300860], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2], 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number (OPP-300860]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Shanaz Bacchus, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 9th fl., CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703] 308-8097, e-mail: bacchus.shanaz @epa.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of February 19, 1999 (64 FR 8358) (FRL-6081-2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA of 1996 (Pub. L. 104-170) announcing the filing of a pesticide tolerance petition by the IR-4, New Jersey Agricultural Experiment Station, Technology Center of New Jersey, Rutgers University, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. The notice included a summary of the petition prepared by the petitioner, IR-4. The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of Aspergillus flavus AF36 in/on cotton in Arizona.

Comments submitted to the Agency regarding the proposed use of the antifungal agent were by the cotton growers in the region who were all in favor of the extension of the temporary exemption from the tolerance. Both the toxigenic and atoxigenic strains are naturally occurring in Arizona. The growers were of the opinion that this technology is likely to reduce the high levels of the naturally occurring, toxin-producing strain of A. flavus by displacement.

I. Background and Statutory Findings

New section 408(c)(2)(A](i] of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ``safe.'' Section 408(c](2)(A](ii) defines ``safe'' to mean that ``there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b](2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ``ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...''. Additionally, section 408 (b)(2)(D) requires that the Agency consider ``available information'' concerning the cumulative effects of a particular pesticide's residues and ``other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the

toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide us in residential settings.

This extension of the temporary exemption from the requirement of a tolerance is associated with an extension of an Experimental Use Permit (69224-EUP-1), published in the Federal Register of February 14, 1996, (61 FR 5771) (FRL-5347-5), which was granted to the Southern Regional Research Center, United States Department of Agriculture, Agricultural Research Service (USDA ARS), 1100 Robert E. Lee Blvd., New Orleans, LA 70179-0687 on May 28, 1996 and expires May 20, 1999. Approximately 1,120 acres of cotton in Yuma County, Arizona, were treated at a rate of 10 pounds (lbs.) of the pesticide per acre over the 3-year period. A temporary exemption from the requirement of a tolerance was established in connection with this EUP as published in the Federal Register of June 14, 1996, (61 FR 30235) (FRL-5377-6). No adverse effects were reported in the annual reports which the registrant submitted as required in the EUP.

[(Page 28372]]

USDA ARS has amended the EUP and extended treatment to a total of 20,000 acres of commercial cotton fields in 5 of the 15 counties in Arizona. The aerial applications are to be made in the following counties: Yuma (3,000 A), LaPaz (1,000 A), Maricopa (9,000 A), Mohave (1,000 A) and Pinal (6,000 A). The antifungal agent is applied prebloom to the soil of treated cotton fields, where the mycelia germinate to displace the naturally occurring toxigenic strain.

Of the strains of A. flavus which abound naturally in Arizona, this atoxigenic L strain comprises 15% of the natural microbial population in the soil, as opposed to the predominant S or toxigenic S strain.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The toxicological profile in support of the extension of the temporary exemption from a tolerance of the residues of the atoxigenic (non-toxin producing) A. flavus AF36 demonstrates that the LD<INF>50</INF> of A. flavus AF36 is greater than 5,000 milligrams/kilograms (mg/kg). No adverse clinical effects were observed after 14 days in rats treated by gavage with the microbial antifungal agent and no abnormalities or adverse effects were observed in any of the rats upon autopsy.

Studies were not conducted to evaluate the potential of the active ingredient as an agent linked to genotoxicity, or reproductive, developmental, subchronic or chronic effects, because the researchers have worked with the proposed microbial antifungal agent for several years in laboratory and field settings with no adverse effects. Also, the organism is a naturally occurring, ubiquitous microbe.

III. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

There is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to A. flavus AF36 from the limited use pattern of the experimental use permit. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

A. Dietary Exposure

1. Food. Application of the microbial pesticide prebloom in the cultural practice precludes the potential for direct residues of A. flavus per se to remain on the treated cotton. The proposed strain of A. flavus, AF36, is atoxigenic, i.e. not producing aflatoxin. Only the seed of the treated commodity, cotton, is likely to be processed as food for cottonseed oil. Residues of A. flavus AF36 or its metabolites are likely to be removed from cotton seed oil during this processing. Moreover, the applications are proposed for 5 of the 15 counties of Arizona only, on 3-7% of the total cotton, thus minimizing any potential dietary exposure. The Food and Drug Administration (FDA) regulates the levels of aflatoxin in cotton seed meal and other commodities associated with the production of cotton. Cottonseed is monitored for aflatoxin content during the ginning process, and all cotton seed from these experiments will be closely monitored for aflatoxin content as part of the experimental program. On the basis of the preceding discussion, dietary exposure to the treated commodity is likely to be minimal to human adults, infants and children. exposure to immunocompromised human adults, infants and children. Moreover, the application of the microbial pesticide to specific counties during the EUP represents application to approximately 3-7% cultivated areas in these counties, thus minimizing exposure.

1. Dermal exposure. Non-occupational dermal exposure and risk to adults, infants and children are not likely if the pesticide is used as labeled. The antifungal agent is a naturally occurring microbe to be applied to the soil of cotton fields prebloom. It is ubiquitous in the environment. If the microbe exhibits dermal sensitizing properties which is associated with this genus of fungi, the boundaries and the large particle size of the spores are likely to maintain distribution near treated areas thus protecting nearby at-risk populations. Based on the low toxicity potential as evidenced by the data submitted, the microbial pesticide active ingredient is likely to pose a minimal to non-existent hazard if used as labeled.

2. Inhalation exposure. Based on the large spore size of AF36, and on the method of application to the soil of cultivated cotton fields prebloom with set boundaries, non-occupational inhalation exposure and risk to human adults, children and infants are likely to be minimal.

IV. Cumulative Effects

There are no other registered products containing Aspergillus flavus isolate AF36 or any other isolates (strains) of the microbial active ingredient. Moreover, data submitted to the Agency demonstrate that this strain does not produce aflatoxin on the crop or in artificial media in the lab. Data submissions also show that this strain has been shown to exclude the aflatoxin-producing strain when it is applied prior to flowering. Thus, the proposed use is not likely to result in appreciable increases in the long-term population of A. flavus on the crop beyond naturally occurring levels. Furthermore, there is no expectation of cumulative effects with other pesticides.

V. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. In this instance, EPA believes there are reliable data to support the conclusion that there are no threshold effects of concern to infants, children and adults when A. flavus AF36 is used as labeled. As a result, the provision requiring an additional margin of exposure does not apply. The label will require applicators and other handlers to wear gloves, a dust/mist filtering respirator with National Institute of Occupational Safety and Health (NIOSH) approval prefix N-95, R-95 or P-95, long sleeved shirt and long pants, and shoes plus

socks so worker exposure should not be a problem. Label language reflecting potential dermal sensitization is also required.

VI. Other Considerations

A. Endocrine Disruptors

EPA does not have any information regarding endocrine effects of this microbial pesticide at this time. The Agency is not requiring information on

[[Page 28373]]

the endocrine effects of this pesticide at this time; and Congress allowed 3 years after August 3, 1996, for the Agency to implement a screening and testing program with respect to endocrine effects.

B. Analytical Method(s)

Starter cultures are screened on the basis of vegetative incompatibility with the toxigenic strain, as well as for aflatoxin by standard procedures, which allow a zero tolerance for aflatoxin production. A. flavus AF36 does not demonstrate vegetative compatibility with the toxigenic S strain and has never been found to produce aflatoxin. According to the data submissions human pathogens are also within regulatory levels.

Treated cotton and its byproducts are screened for aflatoxin prior to introduction into the channels of commerce. FDA does not allow cottonseed products containing aflatoxin at 20 parts per billion [ppb) or higher to be used in dairy rations. FDA regulations also do not allow cottonseed products containing aflatoxin above 300 ppb to be used for feeding beef cattle.

C. Codex Maximum Residue Level

An exemption from temporary tolerance for residues of Aspergillus flavus isolate AF36 on cotton is currently in effect in conjunction with an Experimental Use Permit published in the Federal Register of June 14, 1996 (61 FR 30235).

VII. Objections and Hearing Requests

The new section 408(g) of the FFDCA provides essentially the same process for persons to ``object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) and as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 26, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the hearing clerk, at the address given under the ``ADDRESSES'' section (40 CFR 178.20]. A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ``when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA,

(703) 305-5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP-300860] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ``ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled

Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority

[[Page 28374)]

Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the (tolerance/exemption) in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ``to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ``to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq. , as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the Federal Register. This rule is not a ``major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 14, 1999.

Janet L. Andersen,
Director, Biopesticides and Pollution Prevention Division

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

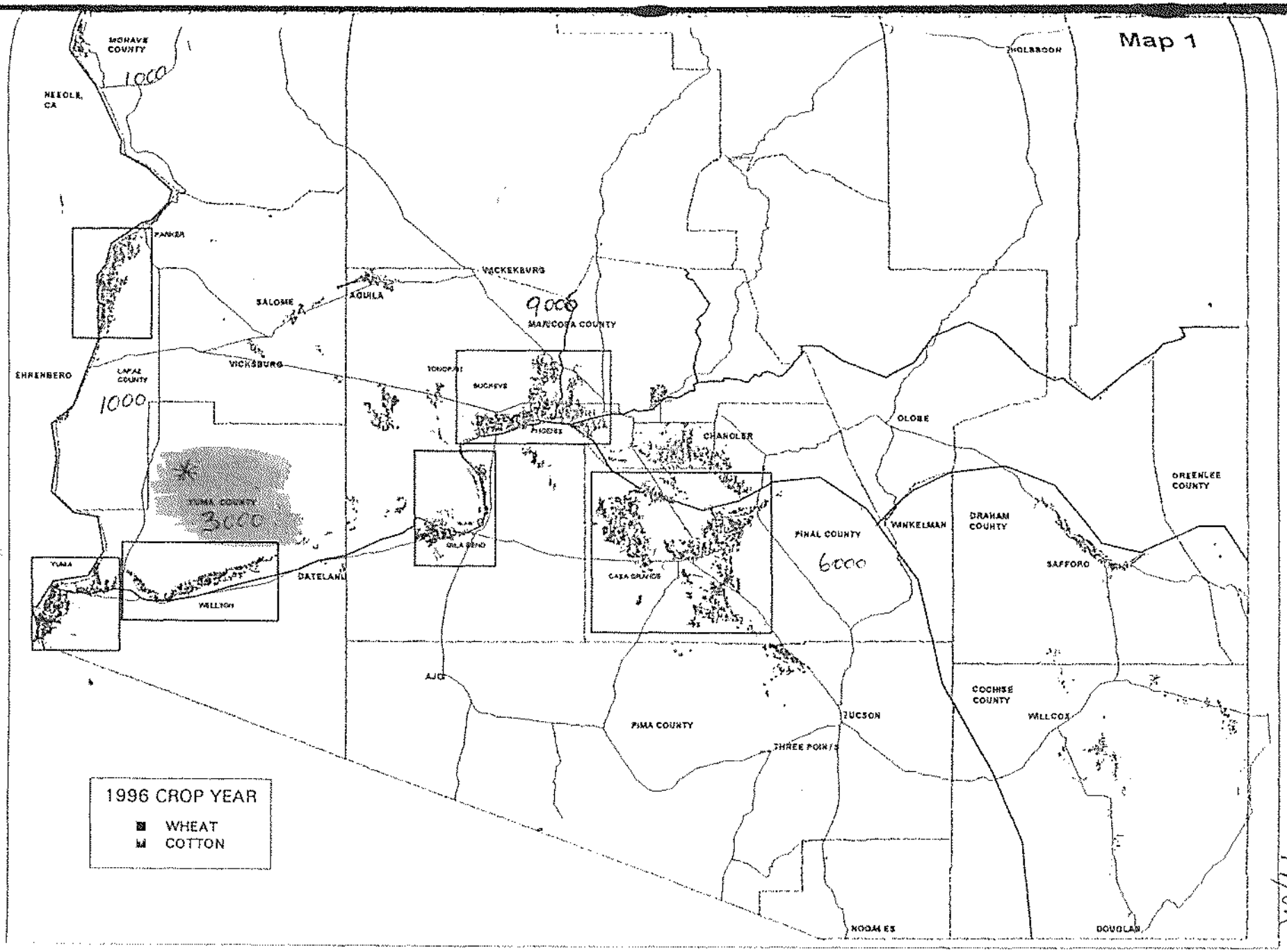
2. Section 180.1206 is added to subpart D to read as follows:

Sec. 180.1206 Aspergillus flavus AF 36; Exemption from the requirement of a tolerance.

Aspergillus flavus AF 36 is temporarily exempt from the requirement of a tolerance in/on cotton when used on cotton in Arizona in accordance with the Experimental Use Permit 69224-EUP-1. The temporary exemption from the requirement of a tolerance will expire on December 30, 2000.

[FR Doc. 99-13192 Filed 5-25-99; 8:45 am]
BILLING CODE 6560-50-F

Map 1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PARKER
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MARICOPA COUNTY
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SUCKEYE
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CASA GRANDE
PINAL COUNTY
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WINKELMAN
DRAHAM COUNTY
GREENLEE COUNTY
SAFFORD
AJO
PIMA COUNTY
TUCSON
THREE POINTS
COCHISE COUNTY
WILLCOX
HOLBROOK
NOGALES
DOUGLAS
1996 CROP YEAR
WHEAT
COTTON

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 30 1999

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dr. Bill Biehn, Coordinator
Interregional Research Project No.4
681 US Highway #1 South
North New Brunswick, NJ 08902

Dear Dr. Biehn:

Aspergillus flavus AF36: EPA EUP No. 69224-EUP-1

Attached are a stamped label and the Experimental Use Permit for the use of *Aspergillus flavus* AF36 on the 5 counties in Arizona. In accordance with PR Notice 98-9, you must include the use of the NIOSH numbers N-95, R-95 or P-95 as appropriate for dust/mist filtering respirators, for the mixer/loader/applicator(s) who handle your product. This permit expires on December 30, 2000. You must submit an annual report as you have done in the past.

If you have any questions, do not hesitate to call me at 703-308-8097.

Sincerely,

Shanaz Bacchus, Chemist/RAL

Encl.

Phil Hutton

02/19/99 10:45 AM

To: Shanaz Bacchus/DC/USEPA/US@EPA, Anne Ball/DC/USEPA/US@EPA
cc:
Subject: Notice of Filing of Pesticide Petitions

---------- Forwarded by Phil Hutton/DC/USEPA/US on 02/19/99 10:49 AM ----------

envsubset
02/19/99 09:54 AM

Please respond to epa-pest2@valley.rtpnc.epa.gov

To: epa-pest2@valley.rtpnc.epa.gov
cc:
Subject: Notice of Filing of Pesticide Petitions

[Federal Register: February 19, 1999 (Volume 64, Number 33)]
[Notices]
[Page 8358-8360]
>From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr19fe99-75]

ENVIRONMENTAL PROTECTION AGENCY

[PF-858; FRL-6057-3]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the amendment of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.
DATES: Comments, identified by the docket control number PF-858, must be received on or before March 22, 1999.
ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

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Comments and data may also be submitted electronically by following the instructions under ``SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ``Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, c/o PM 90, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 5th floor CS1 2800 Crystal Drive, Arlington, VA. (703-308-8097, e-mail: bacchus.shanaz@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received an amendment to a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice, as well as the public version, has been established for this notice under docket control number [PF-858] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ADDRESSES at the beginning of this document.

Electronic comments can be sent directly to EPA at:
opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII File avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number [PF-858]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

Dated: February 9, 1999.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summaries of Petition

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and

[[Page 8359]]

represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Amended Petition

EPA has received a request from the Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, Technology Center of New Jersey, Rutgers University, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390 proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a, to amend 40 CFR part 180 by extending the exemption from the requirement of a temporary tolerance for residues of the microbial pesticide Aspergillus flavus (A. Flavus) AF36 in or on the raw agricultural commodity cotton until December 30, 2001. The request for an extension of the exemption from temporary tolerance was submitted on behalf of the Southern Regional Research Center, United States Department of Agriculture, Agricultural Research Service, 1100 Robert E. Lee Blvd., New Orleans, LA 70179-0687. These extensions are requested to comply with the Food Quality Protection Act of 1996 and to extend the use of the biopesticide to a larger area. Concomitant with this notice of filing, EPA is issuing a notice of receipt of application for extension (amendment) of the Experimental use Permit 69224-EUP-1. According to the proposed amended application for an Experimental Use Permit 69224-EUP-1, 200,000 pounds (90,719 kg) of the microbial pesticide are to be applied to a total of 20,000 acres of commercial cotton fields in 5 of the 15 counties in Arizona. The proposed applications are to be made in Yuma, LaPaz, Maricopa, Mohave and Pinal Counties.

EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act, the Southern Regional Research Center, United States Department of Agriculture, Agricultural Research Service prepared a summary of the petition and authorization for the summary to be published in the Federal Register in a notice of the receipt of the petition. The summary represents the views of the Southern Regional Research Center, United States Department of Agriculture, Agricultural

Research Service; EPA, as mentioned above, is in the process of evaluating the petition. As required by section 408(d)(3) EPA is including the summary as part of this notice of filing. EPA may have made minor edits to the summary for the purpose of clarity.

A. Proposed Use Practices

Aspergillus flavus isolate AF36 is for application to cotton to reduce the incidence of aflatoxin producing strains of A. flavus and thereby reduce aflatoxin contamination of cottonseed. When applied just prior to flowering, A. flavus isolate AF36, which does not produce aflatoxin, competitively excludes aflatoxin producing A. flavus strains without increasing A. flavus in the environment in the long term. Sterile wheat seed colonized with A. flavus strain AF36 is applied at 10 pounds per acre.

B. Product Identity/Chemistry

1. The pesticide and corresponding residues are identified as A. flavus isolate AF36.

2. Aspergillus flavus isolate AF36 is a naturally occurring fungus isolated from cottonseed produced in the Yuma Valley of Arizona. AF36 has been shown to be naturally and consistently associated with commercial cotton grown in Arizona. The overall quantity of A. flavus at time of harvest on cottonseed grown in fields where AF36 has been applied (i.e. colony forming units per gram of seed) has been shown to be similar to levels on cottonseed grown in fields where no application was made. A. flavus is a widespread fungus. It is particularly well adapted to the hot desert regions of Arizona where it is widespread in the environment. The communities of A. flavus in the desert and in agricultural fields are naturally composed of both aflatoxin producing (toxigenic) and aflatoxin non-producing (atoxigenic) strains. Both atoxigenic and toxigenic strains have been found on essentially all plant material and soils in the desert valleys of Arizona. The goal of applications is to increase the percent of A. flavus that is the AF36 strain and to decrease the percent of A. flavus that produces aflatoxins.

3. An extension of the exemption from the requirement of a tolerance for residues of the microbial pesticide A. flavus AF36 in/on cotton is being proposed. A. flavus isolate AF36, when applied to the soil just prior to bloom has been shown to significantly reduce the levels of aflatoxin in cottonseed at harvest. Aflatoxin levels in cottonseed products are regulated by the Food and Drug Administration (FDA). FDA does not allow cottonseed products containing aflatoxin at 20 parts per billion (ppb) or higher to be used in dairy rations. FDA regulations also do not allow cottonseed products containing aflatoxin above 300 ppb to be used for feeding beef cattle. All lots of the active ingredient (A. flavus isolate AF36) and the formulated product are monitored as part of a rigorous quality control program.Starter cultures of A. flavus isolate AF36 used in the production of the end-use product are always screened for aflatoxin production using TLC and appropriate standards. Quality control standards are zero tolerance for aflatoxin production in starter cultures. A. flavus AF36 has never been found to produce aflatoxin. Starter cultures of A. flavus AF36 as well

as end-use products containing this active ingredient are also identified to isolate by vegetative compatibility analysis. Quality control standards are zero tolerance for A. flavus not identified as A. flavus isolate AF36 in the starter cultures and in the formulated product.

C. Mammalian Toxicological Profile

An acute oral toxicity test was performed whereby a single oral dose of 5,000 milligrams/kilogram (mg/kg) per animal of A. flavus isolate AF36 colonized wheat seed was administered by gavage to five male and five female Sprague Dawley rats. The oral LD<INF>50</INF> of A. flavus AF36 was determined to be greater than 5,000 mg/kg rat body weight. No clinical signs were observed during the 14 day study and no abnormalities or adverse effects were observed in any of the rats upon necropsy.

Genotoxicity, reproductive and developmental toxicity, subchronic toxicity and chronic toxicity testing were not performed on this microbial pest control agent. This testing is not warranted, since: (1) A. flavus AF36 has been worked with at the Southern Regional Research Center for over 10 years and in commercial fields (1996 to 1998) and in hand picked field plots (1989 to 1994) without report of any adverse health effects; (2) A. flavus AF36 is widely distributed in the environment and its occurrence is natural; and (3) the label will require applicators and other handlers to wear waterproof gloves, a dust/mist filtering respirator with the appropriate NIOSH

[[Page 8360][

approval prefix N-95, P-95, or R-95, coveralls, long sleeved shirt and long pants, and shoes plus socks so exposure should not be a problem.

D. Aggregate Exposure

1. Dietary Exposure. Aspergillus flavus isolate AF36 is a naturally occurring organism, which does not produce aflatoxin and is thus safer than the A. flavus isolates that produce aflatoxin. Proposed uses and application rates will not result in increases in the total population of A. flavus on the mature crop beyond naturally occurring background levels.

2. Food. FDA does not allow cottonseed products containing aflatoxin at 20 ppb or higher to be used in dairy rations. FDA regulations also do not allow cottonseed products above 300 ppb to be used for feeding beef cattle. A. flavus isolate AF36, when applied to the soil just prior to bloom, has been shown to significantly reduce the levels of aflatoxin in cottonseed at harvest. Furthermore, the proposed use and application rate will not increase exposure of humans to A. flavus by dietary means. There is minimal dietary exposure to A. flavus from cottonseed. There is no mechanism for A. flavus to be transferred from the seed to cow products and there is no evidence that the fungus readily contaminates meats or milk. Seed is typically extracted for oil with hexane and that process kills the fungus. Furthermore, applications of A. flavus AF36 do not increase the indigenous populations of A. flavus associated with the harvested crop.

The applications merely alter the composition of the fungal community associated with the mature crop so that aflatoxin producing strains are far less frequent. The result is a much lower incidence of aflatoxins in the crop and in the environment associated with the developing and mature crop.

3. Drinking Water. Aspergillus flavus isolate AF36 is a naturally occurring organism that is already widespread in the environment and is not considered to be a risk to drinking water. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure of A. flavus through the drinking water. Applications of A. flavus AF36 do not increase the long-term populations of A. flavus in the environment, and thus are not expected to influence the relationship of A. flavus to water sources. Applications merely change the composition of the A. flavus community so that aflatoxins are less common in the environment.

4. Non-dietary exposure. The potential for non-occupational, non-dietary exposure to the general population is not expected to be significant and is not expected to present any risk of adverse health effects.

E. Cumulative Exposure

There are no other registered products containing A. flavus isolate AF36 or any other isolates (strains) of the microbial active ingredient. Data submitted show that the fungal metabolite of concern which is aflatoxin is not produced by A. flavus isolate AF36 in the crop or in artificial media in the lab. When applied prior to flowering, A. flavus isolate AF36 has been shown to exclude aflatoxin producing fungi competitively from the developing crop and to reduce aflatoxin contamination of cottonseed. Data show that the proposed use will not result in appreciable increases in the long-term population of A. flavus on the crop beyond naturally occurring levels. Furthermore, there is no expectation of cumulative effects with other pesticides.

F. Safety Considerations

Aspergillus flavus isolate AF36 is a naturally occurring organism. This isolate has low toxicity as demonstrated by the acute oral toxicity study in rats. A. flavus is ubiquitous throughout the hot desert valleys in Arizona. Studies have shown that treatment of cotton fields just prior to flowering with sterile wheat seed colonized by A. flavus isolate AF36 at 10 lbs. per acre does not increase the long-term populations of A. flavus either on the crop at maturity or in the soil 1 year after application. Based on this information, IR-4 is of the opinion that the aggregate exposure to A. flavus over a lifetime should not change with application of AF36, and exposure to both aflatoxin producing A. flavus strains and aflatoxin should decrease. This should be beneficial to human health. Thus, there is a reasonable certainty that no harm will result from aggregate exposure to A. flavus isolate AF36. Extending the exemption of A. flavus isolate AF36 from the requirement of a temporary tolerance should be considered safe and pose insignificant risk.

G. Existing Tolerances

7

A temporary tolerance exemption on cotton in conjunction with an Experimental Use Permit for A. flavus isolate AF36 is currently in effect (6 t FR 30235-30236, June 14, 1996).

[FR Doc. 99-4158 Filed 2-18-99; 8:45 am]
BILLING CODE 6560-50-F

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

INTERREGIONAL RESEARCH PROJECT NO. 4
New Jersey Agricultural Experiment Station
P.O. Box 231 • New Brunswick • New Jersey 08903 0231
908/932-9575 • FAX: 908/932-8481

8E5001

TO: Shanaz Bacchus

FROM: Bill Biehn (IR-4)

DATE: 7/7/98

NUMBER OF PAGES, INCLUDING THIS COVERSHEET 5

RE: Petition proposing Tolerance Exemption for Aspergillus Flavus isolate AF36 in Cotton

(1) Attached is a Revised Section F where I added a sentence

Please take out Section F (page 16 of 18) in Volume 1 (all four copies) and replace with this attached revised Section F (page 16 of 18).

(2) Attached also is a copy of the Registration Application (Form 8570-1). The OPP identification # is 246110.

(3) Also attached is a copy of the cover letter (transmittal letter) that was sent to EPA with the petition.

16/18

SECTION F

PROPOSED EXEMPTION FROM THE REQUIREMENT OF A

TOLERANCE FOR THE MICROBIAL PEST CONTROL AGENT

ASPERGILLUS FLAVUS ISOLATE AF36 IN OR ON

COTTON

The petitioner, IR-4, on behalf of the United States Department of Agriculture requests the establishment of an exemption from the requirements of a tolerance for the microbial pest control agent Aspergillus flavus isolate AF36 in or on cotton.

This is a tolerance exemption with regional registration for use in Arizona only.

Please read Instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-88

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number: 246110

Application for Pesticide - Section I

1. Company/Product Number: 71693
2. EPA Product Manager: S. Bacchus
3. Proposed Classification: [X] None [ ] Restricted
4. Company/Product (Name): ASPERGILLUS FLAVUS AF36
PM#
5. Name and Address of Applicant (Include ZIP Code):
Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166
[ ] Check if this is a new address
6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(ii), my product is similar or identical in composition and labeling to:
EPA Reg. No.
Product Name

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [ ] Plastic [ ] Glass [X] Paper [X] Other (Specify) Bulk Bags
* Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: [X] Label [ ] Container
4. Size(s) Retail Container: Paper Bag: 50 lbs. Bulk Bags: 1000-3000 lb.
5. Location of Label Directions: [X] On Label [ ] On Labeling accompanying product
6. Manner in Which Label is Affixed to Product: [X] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name	Title	Telephone No. (Include Area Code)
Larry Antilla	Staff Director	602-438-0090

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: Larry Antilla
3. Title: Staff Director
4. Typed Name: Larry Antilla
5. Date: 6-26-98

EPA Form 8570-1 (Rev. 6-84) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

8E5001

Interregional Research Project No. 4
Center for Minor Crop Pest Management

Dr. Janet Andersen
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk
Office of Pesticide Programs - 7504C
U. S. Environmental Protection Agency
401 M. Street (SW)
Washington, DC 20460-0001

JUN 25 1998

RE: Aspergillus flavus isolate AF36 Tolerance Exemption for Cotton

Dear Dr. Andersen:

The undersigned, Dr. W.L. Biehn, Interregional Research Project No. 4, State Agricultural Experiment Station, Rutgers University, New Brunswick, New Jersey 08903, on behalf of the IR-4 Project, the United States Department of Agriculture and the Arizona Cotton Research and Protection Council submit this exemption from the requirement of a tolerance petition pursuant to Section 408 (e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the microbial pesticide Aspergillus flavus isolate AF36.

Since this petition is being submitted in conjunction with the IR-4 Program, no fees should be assessed. Furthermore, it is further requested that fees for submitting and reviewing this petition and application be waived as provided by 40 CFR 152.18(c)(2).

List of Studies Submitted in Support of Proposed Exemption from the Requirement of a Tolerance for Aspergillus flavus isolate AF36.

continued .....

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932 9575 • Fax: 732/932-8481

Dr. Janet Andersen (con't)

Volume No. and Title

Volume 2 - Aspergillus flavus isolate AF36 - Method of Support Information for exemption from the requirement of a tolerance in or on cotton.

Volume 3 - Aspergillus flavus isolate AF 36 - Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 to MRID No. 43763401.

Volume 4 - Aspergillus flavus isolate AF 36 - Analysis of Samples, Certification of Ingredient Limits, Analytical methods for Certified Limits. Amendment No. 2 to MRID No. 43763402.

Volume 5 - Aspergillus flavus isolate AF36 - Safety Information.

Volume 6 - Aspergillus flavus isolate AF36 - Non-target organism and Environmental Safety Information.

Volume 7 - Aspergillus flavus isolate AF36 - Plant Studies - Request for Waiving of the Requirement for Testing.

List of Supplemental Information Submitted in Support of this Petition

1. Notice of Filing* (FQPA Summary)
2. Letter of Authorization

* Notice of Filing is being provided on diskette in Word Perfect 5.1 format under separate cover.

Sincerely,

William L. Biehn

William L. Biehn, Ph.D.
IR-4 Project

WLB:js

cc: Peter Cotty, USDA/ARS
Jane Robens, USDAARS
Larry Antilla, ACRPC
Phil Wakelyn, National Cotton Council

P.S. Volume 7 was previously submitted to EPA under DP Barcode No. D224186 on 8/9/95 in support of a temporary tolerance exemption for Aspergillus flavus isolate AF36 on cotton. Since no MRID Number was previously assigned to this volume entitled Aspergillus flavus isolate AF36 Plant Studies - Request for Waiving of the Requirement for Testing, we are resubmitting this volume and requesting assignment of an MRID number for tracking purposes.

Interregional Research Project No. 4
Center for Minor Crop Pest Management

TO: Shanaz Bacchus

FROM: Bill Biehn (IR-4)

DATE: 4/7/99

NUMBER OF PAGES INCLUDING THIS COVERSHEET: 4

RE: ASPERGILLUS FLAVUS ISOLATE AF36

Attached are the responses by Peter Cotty to the questions faxed to Phil Wakelyn on 4/1/99.

Please call me if you need more information.

Technology Centre of New Jersey
681 U.S. Highway #1 South • North Brunswick, NJ 08902-3390 • 732/932-9575 • Fax: 732/932 8481

THE STATE UNIVERSITY OF NEW JERSEY
RUTGERS

FAX sent 7 April, 1999; cover plus 2 pages

To: William L. Biehn, Ph.D.
IR-4 Project-1st floor
Technology Centre of New Jersey
681 U.S. Highway #1, South
North Brunswick, NJ 08902-3390
Fax: 732-932-8481
Phone: 732-932-9575

From: Peter J. Cotty
Southern Regional Research Center
U.S.D.A., A.R.S.
P.O. Box 19687
New Orleans, LA 70179
Office: 504-286-4391
Lab: 504-286-4556
FAX: 504-286-4419

Bill,

Attached are my responses to the questions from Ms. Bacchus. I sent a copy to Wakelyn as well for his input. I indicated that you will submit the responses tomorrow so we need any feed back by then.

Thanks for the continued efforts. I am in today if you want to discuss these matters.

--Peter.

Responses to Questions from Health Effects Reviewers Regarding Registration of *Aspergillus flavus* AF36: Questions were received via email April 1, 1999.

Question 1: The residue left from evaporating the extract is dissolved in 500 microliters of methylene cloride.

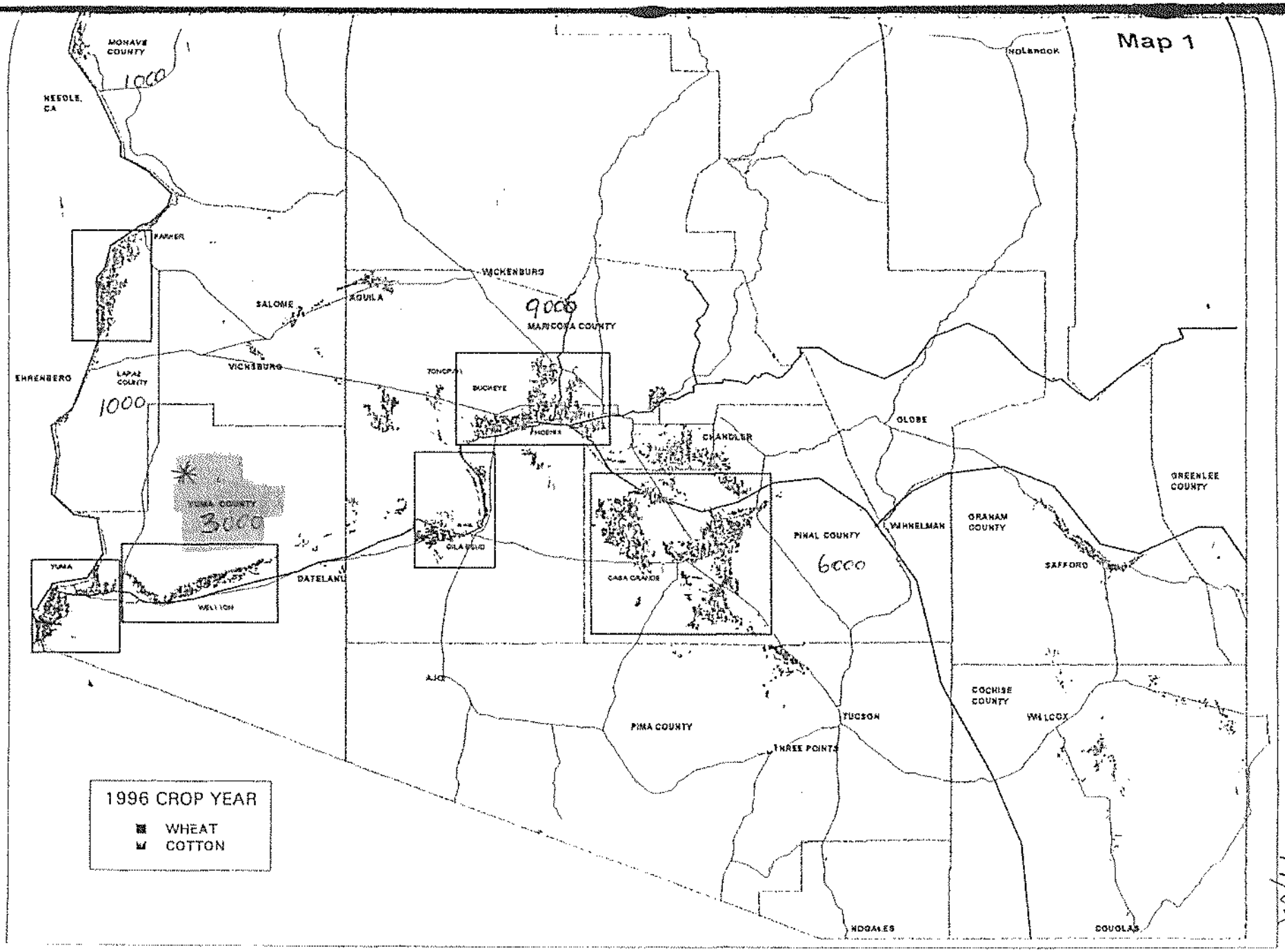
Question 2: In order to confirm that the fungus colonizing the wheat seed is AF36 by vegetative compatibility analysis, the fungal isolates must be mutated into nitrate non-utilizing mutants. The protocol described in Phytopathology 84:1270-1277 is used. Variability is not introduced into the fungi applied to the field in this process because the mutants are not reintroduced to the end-use product. The fungal isolates tested are taken from the quality control samples taken from the end-use product. The second selection medium is called "MIT" it contains Czapek-Dox broth (obtained from Difco), 15 g/L KCLO3, and 20 g/L agar adjusted to pH 6.5. The selection process and it's use in tracking AF36 is described in Phytopathology 84:1270-1277. This article was submitted with the materials supplied for the initial EUP and also in the bound "Summary of Comments by Dr. Peter J. Cotty with Supporting Information and Data Presented at the Meeting Between Agricultural Interests from Arizona and the USEPA Regarding Expanded Use of Aspergillus flavus AF36". The latter was handed out at our meeting on April 15, 1998.

Questions.txt MRID 446261-01 Certification of Limits (151A-15).

1. Aflatoxin standards are purchased from commercial suppliers. A mixture of aflatoxins B_1, G_1, B_2 and G_2 are spotted in two spots on each thin-layer chromatography plate. In all cases 4 ng of aflatoxin B1 is spotted at each location. Depending on the standard mixture (suppliers vary the concentrations of the various aflatoxins) varying concentrations of the other aflatoxins are spotted. However, in all cases all four aflatoxin standards are visible under ultraviolet light and are quantifiable on the developed thin-layer chromatography plates via scanning fluorescence densitometry. The level of detection of aflatoxin in these tests is 1 part per billion. In this assay aflatoxin producers typically produce over 10,000 ppb and a high percentage of aflatoxin producers produce over 100,000 ppb. Each time aflatoxin production is assessed both positive and negative controls are used. The positive control is a simultaneous fermentation in the same batch of medium by a known aflatoxin producing strain, AF13. The negative control is uninoculated fermentation medium.

2. Identification in Final Product. A) For vegetative compatibility analysis, the seed are placed in 2.5-ml sterile water. B) The quantity of water in the vial should not influence detection of non-vegetatively compatible strains. The technique determines if AF36 is the strain colonizing the seed evaluated. This is a plus-minus test. Either the strain colonizing the seed is AF36 (the strain we started with) or it is not. The colonization of a batch of wheat can be

viewed as a single colonization event in which a single suspension of fungal spores colonizes sterilized wheat. The vegetative compatibility tests are directed at assuring that the colonizing fungus is AF36. C) The second selection medium is described above under Question 2. D) The product applied to the field is wheat seed colonized by *Aspergillus flavus* AF36. The viability of the fungus on the wheat seed is determined and the potential for the fungus colonized wheat seed to produce conidia is determined. Those conidia form in the field after application and disperse rapidly after forming. We have not observed lack of viability of *A. flavus* conidia produced on various substrates and have not observed variability in viability of A. flavus conidia produced on wheat. Quantification is done by turbimetry. The spore production is extrapolated from a standard curve that we developed. The standard curve relates turbidity of spore suspensions with colony forming units. Thus the normal variability in spore viability (if any) is included in the measurement.


Map 1
MOHAVE COUNTY
1000
NEEDLE, CA
PARKER
SALOME
AQUILA
WICKENBURG
9000
MARICOPA COUNTY
VICKSBURG
EHRENBERG
LAPAZ COUNTY
1000
BUCKEYE
PHOENIX
CHANDLER
GLOBE
HOLBROOK
YUMA COUNTY
3000
YUMA
WELLTON
DATELAND
GILA BEND
CASA GRANDE
PINAL COUNTY
6000
WINKELMAN
GRAHAM COUNTY
SAFFORD
GREENLEE COUNTY
AJO
PIMA COUNTY
TUCSON
THREE POINTS
COCHISE COUNTY
WILCOX
NOGALES
COUGLAS
1996 CROP YEAR
WHEAT
COTTON

17/63

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 13 1999

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Aspergillus flavus AF36 briefing

Wed. April 14, 1999 @ 10 a.m.
Room 1119, Crystal Mall2

OVERVIEW

- Extension of an Experimental Use Permit (EPA Reg. No. 69224-EUP-1) from 1120 to 20,000 acres in 5 counties of Arizona.
- Extension of the exemption from temporary tolerance (PP# 5E4575) for residues of AF36 on cotton and associated commodities.
- EUPs on areas greater than 5000 acres are the purview of the Office Director.
- Active ingredient is a microbial antifungal agent, *Aspergillus flavus* AF36, grown on wheat seeds and applied aerially at 10 pounds/acre.
- *A. flavus* AF36, a saprophyte, occurs naturally in Arizona. This strain is reported as not producing aflatoxin, a carcinogenic metabolite produced by other strains.
- It is an occasional pathogen of birds, more rarely of some mammals, bees and other insects.
- Birds are likely to be exposed to *A. flavus* AF36 by the oral and inhalation routes. However, avian respiratory problems caused by *A. flavus* are rare or relatively undocumented.
- Bees of several species pollinate cotton. Honey bee hives are rarely infected with an *Aspergillus* spp., causing "stone brood" (dead larva). Weakened bees are reported to be more susceptible.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Aspergillus flavus AF36 briefing

Wed. April 14, 1999 @ 10 a.m.
Room 1119, Crystal Mall2

I. TOPICS FOR DISCUSSION

- Use of non-aflatoxin-producing *Aspergillus flavus* AF36 (AF36) to displace aflatoxin-producing *A. flavus* on cotton
- Extension of an Experimental Use Permit (EPA Reg. No. 69224-EUP-1) from 1120 to 20,000 acres in 5 counties of **Arizona**
- Extension of the exemption from temporary tolerance (PP# 5E4575) for residues of AF36 on cotton and associated commodities.
- Data requirements for Section 3 registration.

II. BPPD Team Members

Regulatory

Phil Hutton	Entomologist, Branch Chief
Shanaz Bacchus	Chemist, Regulatory Action Leader

Science

Health Effects

John Kough	Biologist, Senior Scientist
Michael T. Watson	Plant Pathologist, Health Effects

Ecological Effects

Doug Gurian-Sherman	Plant Pathologist, Ecological Effects
Gail Tomimatsu	Plant Pathologist, Ecological Effects

Internet Address (URL) • http://www.epa.gov
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III. REGISTRANTS

A. **1. Experimental Use Permit** (EPA Reg. No. 69224-EUP-1)

- USDA Southern Regional Research Center, United States Department of Agriculture, Agricultural Research Service (USDA ARS)

- **2. Exemption from temporary tolerance**
  Interregional Research Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, Rutgers University,

B. **1. Proposed Section 3 Registration**

- The Arizona Cotton Research and Protection Council.

- **2. Exemption from tolerance**
  Interregional Research Project No. 4 (IR-4).

IV. DISCUSSION

Background

- EUP issued and exemption from temporary tolerance granted May 20, 1996 valid thru May 20, 1998, yearly reports submitted.

- Yuma county - treated acres at 10 lbs/acre: 100 (Yr.1), 500 (Yr. 2), 500 (Yr. 3)

- **Proposal**: Acres to be treated represent 0.0126 percent of total acres or 11.74 percent of cultivated acres.

Yuma	3,000
La Paz	1,000
Maricopa	9,000
Mohave	1,000
Pinal	6,000

- Exemption from temporary tolerance reproposed to comply with FQPA

- Also proposing Section 3 registration and exemption from tolerance (permanent)

V. SCIENCE ASSESSMENT

A. Human Health Effects and Risk Assessment for *Aspergillus flavus* AF36.

Present Information:

- *Aspergillus flavus* is a saprophytic fungus which is found on living and dead plant material

throughout the world.

- Some strains of *A. flavus* produce carcinogenic metabolites known as aflatoxins. Aflatoxin contamination of cottonseed, grown for cattle feed, is a perennial problem in Arizona.

- *Aspergillus flavus* is an indigenous fungus in the cotton growing regions of Arizona, and strain AF36 is a naturally occurring strain which normally represents approximately 15% of the *A. flavus* population in Arizona cotton fields.

- Unlike some other strains of *A. flavus*, strain AF36 does not produce any aflatoxin.

- Strain AF36 competes with other *A. flavus* strains for sites of infection on the cotton seed, thereby reducing the amount of toxigenic strains of the fungus present in Arizona cotton fields. i.e., application of AF36 does not appreciably increase the overall amount of *A. flavus* present.

- Strain AF36 is an opportunistic pathogen, i.e., scientific and medical literature discuss the ability of the fungus to infect immunocompromised individuals.

- Acute oral toxicity testing indicates an LD_{50} of greater than 5000 mg/kg of rat body weight.

B. Ecological Effects of *Aspergillus flavus* AF36

1. Natural Occurrence and Non-Target Organism Risk Assessment

Applicant has argued that AF36 is a naturally occurring organism, and the proposed use (a single application of wheat seed containing AF36) will not cause increased exposure to *A. flavus*. Reviewed data indicate the following:

- The amount of *A. flavus* in the soil one year after application is essentially the same in AF36 treated fields and untreated fields.

- The amount of *A. flavus* on cotton at crop maturity does not differ in treated and untreated cotton fields.

- The amount of spores produced by *A. flavus* is highest around crop maturity (August - October). Indirect data suggest that use of AF36 does not increase the amount of *A. flavus* spores occurring at crop maturity.

2. Non-Target Organism Risk Assessment: Published literature reports *A.flavus* is an occasional pathogen of birds and, more rarely, of some mammals, bees and other insects. In the absence of the required non-target pathogenicity tests, there is no distinction of AF36 from other *A. flavus* isolates in ability to cause infection. Pulmonary infections of birds occur in poultry houses where high levels of *Aspergillus* spp. spores occur.

- Bird census data for Arizona cotton fields and surrounding areas indicate that native bird species are present and forage in cotton fields during and after the period when treatment with AF36 would occur. Therefore, increased oral exposure of birds to *A. flavus* may occur..

- Birds are exposed to infection by *A. flavus*,via oral and inhalation routes. However, avian and respiratory problems caused by *A. flavus* are rare or relatively undocumented.

- Bees of several species pollinate cotton. Honey bee hives are rarely infected with an *Aspergillus* sp., causing "stone brood" (dead larva). Weakened bees are reported to be more susceptible.

C. RECOMMENDATIONS

1. Regulatory Aspects

- Publish Proposed Section 3 Federal Register Notices

- Collect reviews, manage risk.

Risk Management

- Impose restrictions on the application of the pesticide: not to be applied within xx yards of residential area.

- Use of Personal Proteclion Equipment (PPE) to protect pesticide handlers.

2. Health Effects

Additional Data to Be Gathered during EUP:

- A pulmonary toxicity/pathogenicity study should be completed.

- The fungus should continually be monitored for any change in the ability to produce aflatoxin.

- Spore levels in treated fields should be compared to non-treated fields, including any changes in spore levels during the growing season.

- Spore exposure should be examined. Specifically, what distance spores travel, and identification of any potential effect on residential areas.

3. Ecological Effects

Additional Data Prior to Section 3(c) Registration:

The major basis for the risk assessment is that exposure to *A. flavus* is unchanged with the proposed treatment. Data on natural populations of *A. flavus*, even in Arizona where this extensive survey effort has been done, are highly variable. Additional variability can be caused by transient weather changes.

At least two years of *A. flavus* population monitoring data as follows:

- Avian oral acute toxicity/pathogenicity tests.
- Avian acute pulmonary toxicity/pathogenicity tests..
- Bee hive or brood pathogenicity studies.

Questions:

1. What additional information does management need to help in decision-making process?

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 16 1998

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dr. Bill Biehn, Coordinator
Interregional Research Project No.4
681 US Highway #1 South
North New Brunswick, NJ 08902

Dear Dr. Biehn:

Subject: Pre-registration meeting on *Aspergillus flavus* AF36 on Cotton in Arizona

The Agency has reviewed your submission dated May 7, 1998, regarding the minutes of the meeting with certain members of the Biopesticides and Pollution Prevention Division (BPPD). The points in your submission were numbered 1 through 11 to facilitate communication on certain points. The team members have provided the following comments on the meeting minutes:

Item 3 - "The purpose of the EUP.....need to be evaluated."
Your claim in this project is to eliminate the toxigenic strain of *A. flavus*. It is highly unlikely that you will eliminate aflatoxin. Accurate claims should address reduction of the toxigenic strain or of aflatoxin, and if possible, which of the aflatoxins you plan to reduce.

Item 7 - "Concern was expressed.....Section 3 registration."
A blue folder was presented with anecdotal information to support a request to waive the requirement for the avian toxicity studies. Requests to waive data must be supported by sound scientific information. In your data waiver request, please clarify:
(a) what preferred habitats for birds are available within the treatment area;
(b) the proximity of such habitats to the cotton growing areas;
© what the exposure of birds is likely to be to *A. flavus* AF36 during pesticide application and during the growing season.

Item 8 - "It was also pointed out.....avian toxicology studies."
Clarify whether wheat fields are adjacent to and/or in close proximity to cotton fields in Arizona. Include either a study plan or what procedure you plan to use to monitor the exposure and effects on birds in the treated area.

Item 9 - "Since *A. flavus* occurs.....Experimental Use Permit."
(a) The potential pathogenicity of the active ingredient must be addressed. A label warning of potential pathogenicity and a requirement for appropriate Personal Protective Equipment will be required on labels issued for use of *A. flavus* AF36.

(b) Requests to waive data requirements for environmental fate may be supported by the submission of information regarding the microbial ecology of both aflatoxin-producing and non-aflatoxin producing *A. flavus* in Arizona.

Item 11 - "EPA indicated that a description of the manufacturing.....We agreed to provide it." With reference to the folder entitled "Recommendations for setting up a large-scale AF-36 wheat production facility in Phoenix, Arizona", dated April 1997, the team was of the opinion that the extrapolation from the scale-up from 2 cubic feet to 100 cubic feet may be problematic and that further quality control measures may be required.

It is good that you mention that verification will be requested relative to temperature maintenance within the sterilization procedure. During the scale-up, the time required for cooling from 37°C to 31°C after inoculum addition may increase. It is feasible that without adequate Quality Assurance controls, the potential for contamination by extraneous microorganisms can occur. Since the systems appear to have agitators, it may be possible to cool the hot sterile seeds with HEPA filtered air. If this is not practical and you have alternative proposals, describe what Quality Assurance and Quality Control measures you plan to take to minimize contamination during the manufacturing process.

Also of concern are:
(a) There was some question about whether the manufacturer was aware of the sterile techniques required for solid state fermentation, (see memo dated April 6, 1998, from Joe Ploski (USDA) to Tom Chirkot (Patterson-Kelley Co.). Please verify that steps will be taken to implement those sterile techniques and to train manufacturing staff to maintain those techniques.
(b) Is there an alternative non-porous material to pillow cases for use in the drying oven? Can steps be taken to contain the potential dissemination of spores from the pillow cases during the transport of the AF36-treated wheat seeds to the drying oven?
© Include in your description of the manufacturing process, the steps taken to monitor air quality to ascertain product integrity.
(d) The wheat seeds treated with *A. flavus* AF36 must be differentiated by way of color from other wheat seeds used for planting or processing. Include the amounts of the dye/coloring material used in your Confidential Statement of Formula and a description of the method to color the seeds in your manufacturing process.

If you would like to discuss these matters any further, do not hesitate to call Shanaz Bacchus at 703-308-8097.

Sincerely,

Phil O. Hutton, Chief
Microbial and Plant Pesticides Branch
Biopesticides and Pollution
Prevention Division

FRONT END PROCESSING FORM TO FILE ROOM

DATE 7-1-98

FILE NUMBER 71693-R

_____ No Data - File Room "Make Ready for _____"
(PM or Individual)

✓ Date - File Room "Assign Jacket to Shelf"

_____ Rejected - File Room "Assign Jacket to Rejected Shelf"

FRONT END PROCESSING APPLICATION INFORMATION CHECK

PM 90

EPA COMPANY NUMBER 71693-R

EPA REGISTRATION NUMBER STATUS (For Amendments) Active _____ Cancelled _____

Not in REFS _____

"ME-TOO" CITED PRODUCT STATUS Active _____ Cancelled _____

Not in REFS _____

PRAT RECORD CREATED JCL - 7/1/88

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

07/01/98

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Arizona Cotton Research and Protection Council
2403 W. Huntington Drive
Suite 101
Tempe, AZ 85282-3166

PRODUCT NAME: Aspergillus Flavus AF 36
COMPANY NAME: Arizona Cotton Research and Protection Council
OPP IDENTIFICATION NUMBER: 246110
EPA FILE SYMBOL: 71693-R
EPA RECEIPT DATE: 06/26/98

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT:

The office of Pesticides Programs has received your application for a new registration and it passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process, and does NOT constitute approval.

If you have any questions, please contact Product Manager 90, at (703)-308-8260.

Sincerely,

Front End Processing Staff
Information Resources & Services Division
Information Services Branch

N/FT.

B

ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL

2403 West Huntington, Suite 101,
Tempe, Arizona 85282-3166
(602) 438-0059
(602) 438-0407 - Fax

June 26, 1998

Dr. Janet Anderson
Biopesticide and Pollution Prevention Division
c/o Document Processing Desk (APPL)
Office of Pesticide Programs - 7504C
U.S. Environmental Protection Agency
401 M Street (SW)
Washington, DC 20460-0001

Subject : Aspergillus flavus AF 36
Arizona Cotton Research and Protection Council Application
EPA Company No.: 71693-R

Dear Dr. Anderson:

Enclosed please find our Application for Pesticide Registration for the above subject product. Enclosed also are:

1. product chemistry information,
2. proposed label (five copies);
3. confidential statement of formula;
4. certification with respect to citation of data statement, etc

In support of this application, please refer to the following petition entitled:
"Aspergillus flavus isolate AF 36 / Tolerance Exemption in or on Cotton".

The above petition was submitted by IR-4 on behalf of the USDA and the Arizona Cotton Research and Protection Council.

As per PR Notice 88-4, the registration of the above use is exempt from fees.

Sincerely,

Larry Antilla
ACRPC,
Staff Director

win\Aflatoxin\Use permit

(1) Do we need letter from USDA to support Data Citation?

(2) Who is data owner?

NF

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number: 246110

Application for Pesticide - Section I

1. Company/Product Number: 71693-R

2. EPA Product Manager: ~~S. Bacchus~~

PM#: 90

3. Proposed Classification: [X] None [ ] Restricted

4. Company/Product (Name): ASPERGILLUS FLAVUS AF36

5. Name and Address of Applicant *(Include ZIP Code)*:
Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166
[ ] *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

[●] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging: [ ] Yes* [X] No
** Certification must be submitted*

Unit Packaging: [ ] Yes [X] No
If "Yes" Unit Packaging wgt. / No. per container

Water Soluble Packaging: [ ] Yes [X] No
If "Yes" Package wgt / No. per container

2. Type of Container: [ ] Metal [ ] Plastic [ ] Glass [X] Paper [X] Other (Specify) Bulk Bags

3. Location of Net Contents Information: [X] Label [ ] Container

4. Size(s) Retail Container:
Paper Bag: 50 lbs.
Bulk Bags: 1000-3000 lb.

5. Location of Label Directions: [X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: [ ] Lithograph [X] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name: Larry Antilla
Title: Staff Director
Telephone No. (Include Area Code): 602-438-0059

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature: Larry Antilla
3. Title: Staff Director
4. Typed Name: Larry Antilla
5. Date: 6-26-98

6. Date Application Received (Stamped)

EPA Form 8570-1 (Rev. 6-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: *Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.*

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). (If not exempted by 40 CFR 152.81 (b) (4));
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on [illegible] x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, post or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "one-time," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number
246110

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification ☒ None ☐ Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant *(Include ZIP Code)* ☐ *Check if this is a new address*	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

- ● Amendment - Explain below.
- ☐ Resubmission in response to Agency letter dated _____
- ☐ Notification - Explain below.
- ☐ Final printed labels in response to Agency letter dated _____
- ☐ "Me Too" Application.
- ☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
● ☐ Yes* ☐ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☐ Plastic ☐ Glass ☒ Paper ☒ Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: ☒ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions: ☒ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☒ Lithograph ☐ Paper glued ☐ Stencilled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
4. Typed Name	5. Date

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

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INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). (If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
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SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
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2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

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1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

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2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
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1-5. Self-explanatory.
6. EPA Use Only.

United States
Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0060
Approval Expires 05-31-95

Certification with Respect to Citation of Data

Applicants Name and Address	
Arizona Cotton Research and Protection Council 2403 W. Huntington Drive, Suite 101 Tempe, AZ 85282-3166	EPA File Symbol/Registration Number 71693-R Product Name ASPERGILLUS FLAVUS AF36 Date of Application 6/26/98

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study.

   |X| I am the original submitter*; or

   | | I have obtained the written permission of the original submitter for _____ (insert name of chemical), which is _____ (insert names of companies) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study;

   a. | | I am the original data submitter*; or

   |X| I have obtained the written permission of the original data submitter for Aspergillus Flavus AF36 (insert name of chemical), which is USDA/ARS/SRRC and IR-4 _____ (insert names of companies) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) to cite that study*; or

   b. | | I have notified in writing the companies _____ (insert names of companies) for _____ (insert name of chemical) that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are:

   Companies _____ (insert names of companies) for _____ (insert name of chemical) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)
   Companies _____ (insert names of companies) for _____ (insert name of chemical) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) that have submitted the studies which I have cited (Selective method*).

4. | | I certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired.

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

Signature	Name and Title	Date
[signature]	BARRY ARMIA / DIRECTOR	6-26-98

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature	Name and Title	Date

EPA Form 8570-29 (Rev. 5-94) Electronic and Paper versions acceptable.
Previous editions are obsolete.

★ U.S. GPO 1995-386-620/20404

Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 2.5 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining needed data, and completing and reviewing this application form. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460; and to Office of Management and Budget, Paperwork Reduction Project (2070-0055), Washington, DC 20503, marked "Attention Desk Officer for EPA."

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0060
Approval Expires 05-31-95

Certification with Respect to Citation of Data

Applicants Name and Address	EPA File Symbol/Registration Number 71693 - R
Arizona Cotton Research and Protection Council 2403 W. Huntington Drive, Suite 101 Tempe, AZ 85282-3160	Product Name ASPERGILLUS FLAVUS AF36
	Date of Application 6/26/98

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study.

   [X] I am the original submitter*; or

   [ ] I have obtained the written permission of the original submitter for _____ (insert name of chemical), which is _____ (insert names of companies) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) to cite that study*

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study;

   a. [ ] I am the original data submitter*; or

   [X] I have obtained the written permission of the original data submitter for Aspergillus Flavus AF36 (insert name of chemical), which is USDA/ARS/SRRC and IR-4 (insert names of companies) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) to cite that study*; or

   b. [ ] I have notified in writing the companies _____ (insert names of companies) for _____ (insert name of chemical) that have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are:

   Companies _____ (insert names of companies) for _____ (insert name of chemical) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method*). (Also, sign the General Offer Statement below.)
   Companies _____ (insert names of companies) for _____ (insert name of chemical) (for multiple chemicals link the companies who are original data submitters with the appropriate chemical name) that have submitted the studies which I have cited (Selective method*).

4. [ ] I certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired.

* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

Signature	Name and Title	Date
[signature]	BARRY ANDRIA / DIRECTOR	6-26-98

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Signature	Name and Title	Date

EPA Form 8570-29 (Rev. 5-94) Electronic and Paper versions acceptable.
Previous editions are obsolete.

★ U.S. GPO: 1995-386-820/20404

Paperwork Reduction Act Notice

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DATA MATRIX FOR ASPERGILLUS FLAVUS AF36

Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL (Submitted by Applicant)

Aspergillus flavus isolate AF36 - Manufacturing Process and Discussion on the Formation of Unintentional Ingredients.

Guideline #	MRID No.
151A-11	Submitted on 6/25/98
151A-12	Submitted on 6/25/98

Aspergillus flavus isolate AF36 - Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits

Guideline #	MRID No.
151A-13	Submitted on 6/25/98
151A-15	Submitted on 6/25/98

IR-4 Project, Technology Centre of New Jersey
Rutgers University, 681 U.S. Highway #1 South
North Brunswick, NJ 08902-3390

Obtained from IR-4 (permission letter enclosed)

Aspergillus flavus isolate AF36 - Safety Information

Guideline #	Submitted on
152A-10, 152A-11, 152A-12, 152A-13, 152A-14, 152A-15, 152A-20, 152A-21, 152A-30, 152A-31, 152A-32, 152A-33	6/25/98*

Aspergillus flavus isolate AF36 - Non-target organism and Environmental Safety Information.

Guideline #	Submitted on
154A-16, 154A-17, 154A-18, 154A-19, 154A-20, 154A-21, 154A-22, 154A-23, 154A-24	6/25/98*

* Studies submitted on 6/25/98 have not yet been assigned MRID numbers.

DATA MATRIX FOR ASPERGILLUS FLAVUS AF36

REGISTRANT: Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

USDA/ARS
Southern Regional Research Center
1100 Robert E. Lee Blvd.
New Orleans, LA 70179

Data obtained from USDA-ARS/Southern Regional Research Center (permission letter enclosed)

Aspergillus flavus isolate AF36 - Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients.

Guideline #	MRID No.
151A-10	43763401, 43990001
151A-11	43763401
151A-12	43763403

Aspergillus flavus isoalte AF36 - Analysis of Samples, Certification of Ingredigent Limits, Analytical Methods for Certified Limits and Physical and Chemical Properties.

Guideline #	MRID No.
151A-13	43763402, 43972401
151A-15	43763402, 43972401
151A-16	43763402,
151A-17	43763402, 43972401

DATA MATRIX FOR ASPERGILLUS FLAVUS AF36

REGISTRANT: Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

Data obtained from USDA-ARS/Southern Regional Research Center (permission letter enclosed)

Aspergillus flavus isolate AF36 - Plant Studies - Request for Waiving of the Requirement for Testing.

Guideline #	Submitted on
154A-4, 154A-22	6/25/98*

Aspergillus flavus isolate AF36 - Product Performance Data

Guideline #	MRID No.
156A-2, 156A-3	43763405

* Studies submitted on 6/25/98 have not yet been assigned MRID Numbers

DATA MATRIX FOR ASPERGILLUS FLAVUS AF36

REGISTRANT: Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

Data obtained from USDA-ARS/Southern Regional Research Center (permission letter enclosed)

Aspergillus flavus isolate AF36 - Safety Data in Support of Petition Proposing a Temporary Exemption from the Requirement of a Tolerance for Aspergillus flavus for use in cotton.

Guideline #	MRID No.
152A-10, 152A-11, 152A-12	43763403

Acute Oral Toxicity Study in Rats

Guideline#	MRID No.
152A-10	43972403

Aspergillus flavus isolate AF36 - Hypersensitivity Incidents with Microbial Pest Control Agents - Statement of Finding of No Hypersensitivity.

Guideline #	MRID No.
152A-15	43763404, 43972402

Form Approved. OMB No. 2070-0060. Approval expires 5/98

EPA

U.S. ENVIRONMENTAL PROTECTION AGENCY
REGISTRATION DIVISION (TS-767)
WASHINGTON, D.C. 20460

DATA REFERENCE SHEET

(See instructions on the back of the last page before completing.)

1. PAGE 1 OF 6

2. EPA REGISTRATION NO./FILE SYMBOL 71693-R

3. APPLICANT'S NAME AND ADDRESS
Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

4. PRODUCT NAME
Aspergillus flavus AF36

5. PRODUCT MANAGER
Shanaz Bacchus

6. TO ACCOMPANY APPLICATION FOR REGISTRATION DATED:

7. NAME OF STUDY	SOURCE OF STUDY: a. APPLICANT CONDUCTED STUDY (mark 'X')	b. OBTAINED FROM EPA (mark 'X')	c. OBTAINED FROM ANOTHER FIRM OR SOURCE (give name and address)	d. OBTAINED FROM PUBLIC LITERATURE (give reference)	e. OTHER (explain)	f. ACCESSION NUMBER (if known)
Aspergillus flavus isolate AF36 - Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients.			USDA/ARS, Southern Regional Research Center, 1100 Robert E. Lee Blvd. New Orleans, LA 70179			4 3 7 6 3 4 0 1
Aspergillus flavus isolate AF36 - Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits and Physical and Chemical Properties.			USDA/ARS, Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			4 3 7 6 3 4 0 2

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REGISTRATION DIVISION (TS-767)
WASHINGTON, D.C. 20460

DATA REFERENCE SHEET

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1. PAGE 2 OF 6

2. EPA REGISTRATION NO./FILE SYMBOL 71693-R

3. APPLICANT'S NAME AND ADDRESS
Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

4. PRODUCT NAME
Aspergillus flavus AF36

5. PRODUCT MANAGER
Shanaz Bacchus

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Aspergillus flavus isolate AF36 - Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients - Amendment No. 1 to MRID No. 43763401.			USDA/ARS, Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			43990001
Aspergillus flavus isolate AF36 - Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits - Amendment No. 1 to MRID No. 43763402.			USDA/ARS, Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			43972401

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Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

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Shanaz Bacchus

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Aspergillus flavus isolate AF36 - Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 to MRID No. 43763401.	X					Submitted 6/25/98
Aspergillus flavus isolate AF36 - Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits. Amendment No. 2 to MRID No. 43763402.	X					Submitted 6/25/98

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1. PAGE 4 OF 6

2. EPA REGISTRATION NO./FILE SYMBOL 71693-R

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Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

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Aspergillus flavus AF36

5. PRODUCT MANAGER
Shanaz Bacchus

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Aspergillus flavus isolate AF36 - Safety Data in Support of			USDA/ARS Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			4 3 7 6 3 4 0 3
Petition proposing a Temporary Exemption from the Requirement of a						
tolerance for Aspergillus flavus for use in cotton.						
Acute Oral Toxicity Study in Rats			USDA/ARS Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			4 3 9 7 2 4 0 3
Aspergillus flavus isolate AF36 - Hypersensitivity Incidents with			USDA/ARS Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			4 3 7 6 3 4 0 4
Microbial Pest Control Agents - Statement of Finding of No Hypersensitivity.						

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1. PAGE 5 OF 6

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Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

4. PRODUCT NAME
Aspergillus flavus AF36

5. PRODUCT MANAGER
Shanaz Bacchus

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Aspergillus flavus isolate AF36 - Hypersensitivity Incidents with			USDA/ARS Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			43972402
Microbial Pest Contrl Agents - Statement of Finding of No Hypersensitivity - Amendment No. 1 to MRID No. 43763404.						
Aspergillus flavus isolate AF36 - Safety Information.			IR-4 Project, Technology Centre of New Jersey, Rutgers University, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390			Submitted 6/25/98
Aspergillus flavus isolate AF36 - Non-target organism and Environmental Safety Information.			IR-4 Project, Technology Centre of New Jersey, Rutgers University, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390			Submitted 6/25/98

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Arizona Cotton Research and Protection Council
2403 W. Huntington Drive, Suite 101
Tempe, AZ 85282-3166

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Aspergillus flavus isolate AF36 - Plant			USDA/ARS, Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			Submitted 6/25/98
Studies - Request for Waiving of the Requirement for Testing.						
Aspergillus flavus isolate AF36 - Product			USDA/ARS, Southern Regional Research Ctr., 1100 Robert E. Lee Blvd. New Orleans, LA 70179			437634 05
Performance Data.						

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