PP# 4C5E

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

AUG 24 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM:

SUBJECT: *PP2F04086: Propiconazole in/on Oats. Amendment Dated April 7, 1995; Response to CBTS Review #14941.* **CBTS** #16058; **DP Barcode** #D2118453; **No MRID #**

FROM: María Isabel Rodríguez, Chemist
Tolerance Petition Section III
Chemistry Branch I -- Tolerance Support
Health Effects Division (7509C)

María I. Rodríguez 8-24-1995

THROUGH: Philip V. Errico, Head
Tolerance Petition Section III
Chemistry Branch I -- Tolerance Support
Health Effects Division (7509C)

Philip V. Errico

TO: Connie Welch/Kathryn Scanlon
Product Management Team #21
Fungicide-Herbicide Branch
Registration Division (7505C)

The petitioner, Ciba Corporation, is responding to CBTS Review #14941 (PP2F04086, M.I. Rodríguez, 3-16-95, DP Barcode #D210742) with submission of a revised Section F proposing the following tolerances for propiconazole: 0.1 ppm in/on oats grain, 1.0 ppm in/on oats straw, 10.0 ppm in/on oats forage, and 30.0 ppm in/on oats hay.

DISCUSSION/CONCLUSIONS:

In CBTS Review #14941, due to the absence of residue data for oats hay, CBTS did not recommend for tolerances on other oats commodities in addition to oats grain, straw, and forage. The petitioner was informed of two options regarding this issue: (1) propose a tolerance of 30 ppm for oats hay (based on a dry down factor of 3X for oats forage) or (2) place a feeding restriction for oats hay on the Tilt labels while residue data are being generated. In the latter case the tolerances for oats

grain, forage, and straw should be established with an expiration date with the permanent tolerance contingent upon submission of adequate data for oats hay.

As indicated above, the petitioner has submitted a revised Section F proposing a tolerance for propiconazole in/on oats hay at 30.0 ppm. Therefore, the deficiency is considered to be resolved. No additional information is required from the petitioner on this matter.

RECOMMENDATIONS:

Toxicological considerations permitting, CBTS recommends for the establishment of tolerances for the fungicide propiconazole [1-{(2-[2,4-dichlorophenyl]-4-propyl-1,3-dioxolan-2-yl)methyl}-1H-1,2,4-triazole], and its metabolites determined as 2,4-dichlorobenzoic acid in/on oats grain at 0.1 ppm, straw at 1.0 ppm, forage at 10.0 ppm, and hay at 30.0 ppm.

A DRES analysis, as recommended by CBTS, has already been performed using 0.1 ppm as the residue level for oats grain. (For details refer to Memorandum by J.M. Wintersteen, DRES/SAB/HED to K. Scanlon, PMT #21/FHB/RD, dated 5-1-95).

cc: MIRodríguez, PP2F4086, Reading File, Circulation.

RDI: PVErrico (8-24-95)
MIRodríguez: Draft (8-23-1995), Edited (8-24-1995).
Mail Code 7509C; Tel (703)-305-6710; CM #2, Rm 804-T.

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PP2F4086

August 9, 1995

OFFICE OF PESTICIDE PROGRAMS

CONCURRENCE AND COMMENT ROUTING SHEET

TO: Edward Zager (HED/CBTS)

FROM: Kathryn Scanlon (RD/FHB/PM-21)

SUBJECT: Draft FRN for Pesticide Tolerances for Propiconazole on Oats (2F4086)

Please concur and/or comment, as indicated, on the attached document. If you do not concur, attach a written explanation of your position. If you have been asked to comment, attach your comments. Please return this sheet with your comments to Kathryn Scanlon (Room 233/MC:7505C/305-7382) by August 23, 1995.

Each reviewer who is asked to concur is limited to concurring or non-concurring on matters within his/her area of expertise as defined by job. Division directors, or their designees, may concur or non-concur with respect to matters outside their expertise.

Division, Office or Individual	You have been asked to:		Division, Office or Individual Response			Signature and Date
	Concur	Comment	Concur	Non-Concur	Comment Attached	
[redacted] CBTS	✓	✓				
Phillip Errico Section Head III	✓	✓				
Maria Isabel Rodriguez, Reviewer	✓	✓			✓*	MIR 8-16-95

*Please see comments/recommendations on pages 1, 3, 4, 5, and 8.

Thanks,
MIR

TYPE B - F PETITION -FINAL RULE

40 CFR PART 180

[PP 2F4086/R]

RIN 2070-

Propiconazole is not an ANSI-accepted name. Therefore, the chemical name should be used instead. Please make corrections as needed.

PESTICIDE TOLERANCES FOR ~~PROPICONAZOLE~~ 1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1H-1,2,4-triazole

AGENCY: Environmental Protection Agency (EPA)

ACTION: Final Rule

SUMMARY: This rule establishes tolerances for combined residues of the fungicide ~~propiconazole~~ 1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1H-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in or on the raw agricultural commodities oat grain at 0.1 parts per million (ppm), oat straw at 1.0 ppm, oat forage at 10.0 ppm, and oat hay at 30.0 ppm. Ciba-Geigy Corp. submitted a petition pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA) for the regulation to establish a maximum permissible level for residues of the fungicide.

EFFECTIVE DATE: This regulation becomes effective (insert date of signature in the *Federal Register*).

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 2F4086/R], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections 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 should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to Rm. 1132, CM#2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of any objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of

encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the document number [PP 2F4086/R]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Connie B. Welch, Product Manager (PM) 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 227, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305-6226; e-mail: welch.connie@.epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice of filing, published in the *Federal Register* of ~~June 15, 1995 (60 FR 31465),~~ which announced that Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419 had submitted pesticide petition PP 2F4086 to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), establish tolerances for residues of the fungicide propiconazole (1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1H-1,2,4-triazole) in or on the raw agricultural commodities oat grain at 0.1 ppm, oat straw at 1.0 ppm, oat forage at 10.0 ppm, and oat hay at 30.0 ppm.

- There were no comments received in response to the notice of filing.

The scientific data submitted in the petition and other relevant material have been evaluated. The data considered in support of the tolerance include:

1. Plant and animal metabolism studies.

2. Residue data for crop and livestock commodities.

3. Two enforcement methods and multiresidue method testing data.

4. A 90-day rat feeding study with a no-observable-effect level (NOEL) of 12 mg/kg/day.

5. A 90-day dog feeding study with a NOEL of 1.25 mg/kg/day.

6. A rabbit developmental toxicity study with a maternal NOEL of 100 mg/kg/day and a developmental toxicity NOEL of greater than 400 mg/kg/day

(highest dose tested) (HDT)).

7. A rat teratology study with a maternal NOEL of 30 mg/kg/day and a developmental toxicity NOEL of 30 mg/kg/day.

8. A two-generation rat reproduction study with a reproductive NOEL of 125 mg/kg/day (HDT) and a developmental toxicity NOEL of 25 mg/kg/day.

9. A 1-year dog feeding study with a NOEL of 1.25 mg/kg/day.

10. A two-year rat chronic feeding/carcinogenicity study with a NOEL of 5 mg/kg/day with no carcinogenic potential under the conditions of the study up to and including approximately 125 mg/kg/day, the highest dose tested.

11. A two-year mouse chronic feeding/carcinogenicity study with a NOEL of 15 mg/kg/day and with a statistically significant increase in combined adenomas and carcinomas of the liver in male mice at approximately 375 mg/kg/day, the highest dose tested.

12. Ames test with and without activation, negative.

13. A mouse dominant-lethal assay, negative.

14. Chinese hamster nucleus anomaly, negative.

15. Cell transformation assay, negative.

Ciba-Geigy submitted information which resolved the previously outstanding concerns about the nature of the residue in ruminants, an explanation of recovery calculations, and an explanation of the crop field trial protocol. Data gaps exist concerning dosing in the mouse carcinogenicity study. These data requirements were required under reregistration, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq.

use the chemical name

✓ As part of EPA's evaluation of potential human health risks, ~~propiconazole~~ has been the subject of five Peer Reviews and one Scientific Advisory Panel (SAP) meeting.

use the chemical name

✓ ~~Propiconazole~~ was originally evaluated by the Peer Review Committee on January 15, 1987, and classified as a Group C (possible human) carcinogen with a recommendation made for the quantification of estimated potential human risk using a linearized low-dose extrapolation. The method resulted in the establishment of a Q^* of 7.9×10^{-2} $(mg/kg/day)^{-1}$.

The Peer Review Committee's decision was presented to the FIFRA Scientific Advisory Panel on March 2, 1988. The Panel did not concur with the committee's overall assessment of the weight-of-evidence on the carcinogenicity of propiconazole. The Panel recommended placing the chemical in Group D, indicating that the Group C classification was based on minimal evidence. The Panel's determination that EPA's Group C classification was based on minimal evidence was due to the fact that the incidence of liver tumors in male mice only occurred when the mice were given an excessive chemical dose.

Use the chemical name.

As part of a fifth Peer Review, EPA considered additional information provided by the registrant in support of the registrant's argument that the high dose was excessively toxic in the mouse carcinogenicity study. It further argued that the data from the high dose (2,500 ppm) should not be included in the evaluation of carcinogenic potential of propiconazole. In support of these arguments, the registrant provided two subchronic oral toxicity studies in mice. Ciba-Geigy also provided a reread of the pathology slides from a mouse oncogenicity study which it felt indicated sufficient concurrent liver toxicity at 2,500 ppm to document that this dose was excessive. These findings were not present in the original pathology report. Owing to the inconsistency in Ciba-Geigy's report and the original report, the Agency requested that an independent (third) evaluation of the pathology slides be made to determine if the pathology reported could be confirmed. The results of this (third) pathology evaluation were used in the fifth Peer Review in place of data resulting from the earlier evaluations provided by Ciba-Geigy.

The Peer Review Committee considered the following facts regarding the toxicology data on propiconazole in a weight-of-evidence determination of carcinogenic potential: → Use the chemical name.

1. Increased numbers of adenomas (increased trend and pairwise comparison) were found in the livers of male CD1 mice given 2,500 ppm of propiconazole in their diet.
→ Use the chemical name.

2. The treated animals had earlier fatalities than the controls.

3. The numbers of carcinomas were increased (trend only) in male mice only at the 2,500 ppm dose level. Tumors were not significantly increased at the 500 ppm dose level. Adenomas observed in the treated animals were larger and more numerous than those in controls; however, the tumor type (adenoma) was the same.

4. No excessive number of tumors was found in female mice.

5. In a rat study conducted with acceptable doses of propiconazole, no
→ Use the chemical name.

excessive numbers of tumors were found.

The Peer Review Committee determined, based on the additional information submitted by Ciba-Geigy from two 90-day subchronic studies in mice that the 2,500 ppm dose used in the 2-year chronic study exceeded the maximum tolerated dose (MTD) based on the endpoint of hepatic necrosis, and the 500 ppm dose used in the chronic study was inadequate to assess the carcinogenicity of propiconazole. Use the chemical name. Based on the third pathology evaluation of the chronic study, the Peer Review Committee disagreed with Ciba-Geigy's argument that the study showed excessive toxicity at the 2,500 ppm dose. However, the Peer Review Committee concluded that the 90-day subchronic studies are a better measure of what would be an MTD.

Based upon these findings, the Peer Review Committee agreed that the classification for propiconazole should remain a Group C (possible human) carcinogen and recommended against the previously used Q* (viz. 0.079) for risk assessment purposes. For the purpose of risk characterization the Peer Review Committee recommended that the reference dose (RfD) approach should be used for quantification of human risk. This decision was based on the disqualification of the high dose (2,500 ppm), making the data inappropriate for the calculation of Q*. Because the middle dose (500 ppm) was not considered sufficiently high enough for assessing the carcinogenic potential of propiconazole, EPA has requested an additional mouse study at intermediate dose levels in male mice only. EPA does not expect that these data will significantly change the above cancer assessment that propiconazole poses a negligible risk to humans. Use the chemical name. Use the chemical name. Use the chemical name.

The reference dose for propiconazole is 0.013 mg/kg/day, and based on a NOEL of 1.25 mg/kg/day and an uncertainty factor of 100. The NOEL is taken from a 1-year dog feeding study that demonstrated irritation of the stomach in males as an endpoint effect. The Anticipated Residue Contribution (ARC) from the current action is estimated at 0.000872 mg/kg/day and utilizes 7% of the RfD of the general population of the 48 states. The ARC for the most highly exposed subgroup, non-nursing infants < 1 year is 0.00409 mg/kg/day (31% of the RfD).

The nature of the residue in plants and animals is adequately understood and adequate analytical methods (gas chromatography) are available for enforcement purposes. Secondary. Adequate animal tissue, milk, and egg tolerances exist to cover residues in those commodities incurred from the proposed uses.

The enforcement methodology has been submitted to the Food and Drug Administration for publication in the Pesticide Analytical Manual, Volume II (PAM II). Because of the long lead time for publication of the method in PAM II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide

Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202 (703) 305-5232.

There are presently no actions pending against the continued registration of this chemical.

Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR 180 will protect the public health. Therefore, the tolerances are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections to the 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 above (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). If a hearing is requested, the objections must include a statement of the factual issue(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 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number, [PP 2F4086/R] (including objections and hearing requests 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 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. the public record is located in room 1132 of the Public response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Written objections and hearing requests, identified by the document control number, [PP 2F4086/R], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC

20460.

A copy of electronic objections and hearing requests can be sent directly to EPA at:

opp-docket@epamail.epa.gov.

A copy of electronic objections and hearing requests may be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all objections and hearing requests submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

LIST OF SUBJECTS IN 40 CFR PART 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated:_____

_____

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR Part 180 is amended as follows:

PART 180--[AMENDED]

1. The authority citation for Part 180 continues to read as follows:

AUTHORITY: 21 U.S.C. 346a and 371.

2. Section 180.434 by amending the table there in by adding and alphabetically inserting new entries for oat, grain, oat, straw, ~~and~~ oat, forage, and oat, hay read as follows:

§180.434 ~~Propiconazole~~ 1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1H-1,2,4-triazole; tolerances for residues.

* * * * *

Commodity	Parts per million
Oat, grain	0.1
Oat, straw	1.0
Oat, forage	10.0
Oat, hay	30.0

* * * * *

[FR Doc.95-????? Filed ??-??-95; 8:45 am]

BILLING CODE 6560-50-F

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PP 4086

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

MAR 16 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: *PP2F04086: Propiconazole in/on Oats. Amendment Dated July 15, 1994; Response to CBTS #s 9325/9603.*
CBTS #14941; **DP Barcode #**D210742
MRID #s433142-00, 433142-01, & 433142-02

FROM: María Isabel Rodríguez, Chemist
Tolerance Petition Section III
Chemistry Branch I -- Tolerance Support
Health Effects Division (7509C)
María I. Rodríguez
March 15, 1995

THROUGH: Edward Zager, Acting Chief
Chemistry Branch I -- Tolerance Support
Health Effects Division (7509C)
R. Loranger for

TO: Susan Lewis/Denise Greenway
Product Management Team #21
Fungicide-Herbicide Branch
Registration Division (7505C)

and

Jane Smith, Acting Section Head
Registration Section
Risk Analysis and Characterization Branch
Health Effects Division (7509C)

The petitioner, Ciba Corporation, is responding to CBTS Review #s 9325/9603 (PP2F04086, R. Lascola, 7-20-1993) with submission of additional storage stability data as well as administrative materials including Sections B and F. Additionally, the petitioner is adding the proposed use of Tilt Gel (EPA Reg. No. 100-737) to this petition claiming that the proposed use directions are identical to those proposed for Tilt (EPA Reg. No. 100-617).

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BACKGROUND:

In CBTS Review #s 9325/9603, the petitioner proposed tolerances for the fungicide propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole), and its metabolites determined as 2,4-dichlorobenzoic acid in/on oat grain at 0.1 ppm and straw at 1.0 ppm.

CONCLUSIONS/RECOMMENDATIONS:

Although deficiencies associated with PP2F4086 have been resolved for the establishment of tolerances for the fungicide propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole), and its metabolites determined as 2,4-dichlorobenzoic acid (DCBA) in/on oat grain at 0.1 ppm, straw at 1.0 ppm, and forage at 10.0 ppm, data are not available for the feed item oat hay. Due to the absence of residue data for oat hay (see Section entitled *Other Considerations* at the end of this review), we can not recommend for the tolerances on other oat commodities. The petitioner has two options regarding this issue: (1) propose a tolerance of 30 ppm for oat hay (based on a dry down factor of 3X for oat forage) or (2) place a feeding restriction for oat hay on the Tilt labels while residue data are being generated. In the latter case the tolerances for oat grain, forage, and straw should be established with an expiration date with the permanent tolerance contingent upon submission of adequate data for oat hay.

CBTS recommends that a DRES run be initiated using 0.1 ppm as the residue level for oat grain.

DISCUSSION:

In CBTS Review #s 9325/9603 the petitioner was requested to submit the following information. The petitioner's comments to those questions/requests, as well as the CBTS's response to their comments, follow.

* Conclusion #5:

"The petitioner has not submitted adequate storage stability data. Previously submitted data for peanuts and soybeans can not be translated to the oat grain and straw samples. In PP1F3974, the petitioner indicated that a storage stability study for grass straw and forage is nearing completion. CBTS could translate these data to oats; however, to assure timely resolution of this deficiency, the petitioner should conduct storage stability studies on oats or another cereal grain crop."

* Petitioner's Response to Conclusion #5:

The following study was submitted for review:

> Wurz, R.E.M. June 7, 1994. *Stability of Total Residues of Propiconazole in Weathered Grass Straw, Forage and Seed Samples Under Freezer Storage Conditions.* Study Performed and Submitted by Ciba-Geigy Corporation, NC. Lab Project ID #ABR-94008. MRID #433142-01

A freezer storage stability study was performed to determine the stability of residues of propiconazole in grass forage, straw and seed samples. The study was initiated in December, 1990 with propiconazole and 2,4-dichlorobenzoic acid. Propiconazole 3.6E was the formulation used in the study.

Rye and tall fescue were grown under normal agricultural conditions for grasses grown for seed. Pre-harvest intervals (PHI) for grass straw and seed were 14 days. Grass forage was sampled at a PHI of 145 days. The samples were stored in polyethylene bags. The freezer temperature conditions (-20 °C) were identical to those in the corresponding residue field test samples. For each interval, subsamples were taken from the bulk sample bags.

Analyses were performed according to Method AG-454-B. Briefly, samples were extracted by refluxing with 20% ammonium hydroxide/methanol for one hour. The mixture was then cooled and filtered and an aliquot was evaporated to dryness. The residue was dissolved in aqueous sodium hydroxide and heated for 1.25 hours with potassium permanganate. After dilution with water, the sample was partitioned with 10% diethyl ether/hexane and the organic solution containing DCBA was collected. The sample solution was evaporated to dryness and methylated with diazomethane in the presence of dodecane (to reduce volatility). The sample was cleaned-up on an acidic alumina Sep-Pak before being analyzed by capillary gas chromatography with electron capture (GC/EC) detection. The limit of quantitation for the method was 0.05 ppm propiconazole equivalents. Method recoveries (corrected for control values) of propiconazole as DCBA ranged from 62 to 145% for freshly fortified controls of grass forage, straw, and seed fortified at 0.1, 0.2, 0.5, 2, 10, 20, 25, 50, and 100 ppm.

Results of the analyses for grass forage, straw, and seed samples are summarized as follows.

For the uncorrected values:

Storage Interval *(days)*	Grass Substrate	Uncorrected Values *(ppm)*				
		1X(A)	1X(B)	2X(A)	1X(A) aerial	1X(B) aerial
0	Forage	0.75	0.55	0.80	1.00	0.88
167	Forage	0.92	0.62	0.85	1.00	0.69
255	Forage	1.05	0.69	0.98	1.06	0.75
528	Forage	0.83	0.58	0.87	0.89	0.67
789	Forage	0.70	0.54	0.82	0.83	0.70
1175	Forage	0.99	0.83	1.02	0.61	0.87
0	Straw	30	17	78	23	17
124	Straw	37	14	71	21	17
243	Straw	29	15	50	19	14
526	Straw	29	20	85	26	20
784	Straw	27	12	52	21	18
1166	Straw	33	18	79	25	20
0	Seeds	29	32	47	17	19
314	Seeds	25	26	41	10	15
517	Seeds	24	25	37	13	15
771	Seeds	27	25	38	15	15
1149	Seeds	23	27	35	14	15

There was no appreciable change in the concentration of propiconazole residues in grass seed over the freezer storage period. In grass forage and straw, residues of propiconazole generally increased over the storage period.

Plots of residues of propiconazole determined in the grass commodities versus freezer storage time as well as corrected values expressed in ppm and in percentage recovery were also included in the submitted report. Representative chromatograms and calibration curves were also submitted for review.

Study results show that propiconazole residues are stable in grass forage, straw, and seed samples stored under freezer storage conditions (-20 °C) for a period up to 39 months.

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* CBTS's Response #5:

Oat samples were stored for up to 19 months under conditions identical to those described in the study reviewed above for grass commodities. Therefore, since the duration of the grass storage stability study exceeds that of the maximum oat field residue trial sample storage interval, the oat field trial data previously submitted are adequately supported by storage stability data. No additional frozen storage stability data are required to support the requested information.

The deficiency is considered to be resolved.

* Conclusion #6:

"CBTS has found the following deficiencies in the proposed labeling. The petitioner must remove uses of thiabendazole and thiophanate-methyl on barley, rye, and oats as there are no tolerances for those chemicals on those commodities. Also, the petitioner should clarify that only one application of propiconazole at 50 g ai/A is allowed per season for control of foot rot. The petitioner should also express the time of applications as days before harvest as well as by plant growth stage, and indicate the amount and kind of solvent used to dilute the product (if any is used)."

* Petitioner's Response to Conclusion #6:

The petitioner submitted a revised Section B for review.

The proposed label was modified to clarify that thiabendazole and thiophanate-methyl are approved only for use on wheat, for which tolerances exist. The proposed label was modified to read: "Important: To avoid possible illegal residues: (1) Do not apply more than 50 g ai of propiconazole per acre per season. (2) Do not apply to oats within 40 days of harvest." A discussion of dilution solvents (water) is found in the "General Information" Section of the label.

* CBTS's Response #6:

All the submitted amendments are supported by previously reviewed residue data. Therefore, the deficiencies outlined in Conclusion #6 are considered to be resolved.

* Conclusion #7b:

"The petitioner has also submitted residue data on oat forage. These data would support a tolerance of 10.0 ppm, if the petitioner wishes to remove the label restriction against feeding oat forage. In this case, appropriately revised Sections B and F should be submitted to the Agency."

* Petitioner's Response to Conclusion #7b:

The petitioner submitted revised Sections B and F for review.

In the revised label, the restriction against feeding treated oat forage has been removed and a revised Section B contains a section named "Important," under which the statement "Propiconazole treated oat forage may be grazed or fed to livestock." was included. In addition, the revised Section F proposes a tolerance for residues of the fungicide propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound equivalent in or on the raw agricultural commodity oat forage at 10.0 ppm.

* CBTS's Response #7b:

The deficiency is considered to be resolved.

* Conclusion #7d:

"CBTS can not recommend for appropriate tolerance levels for propiconazole in oats grain and straw until storage stability (Conclusion 5) and proposed labeling (Conclusion 6) deficiencies have been corrected."

* Petitioner's Response to Conclusion #7d:

The petitioner claims that the arguments provided above for Conclusions #5, 6, and 7b should resolve the issues associated with this petition and CBTS should recommend that tolerances be established for propiconazole in oat forage, straw, and grain at 10.0, 1.0, and 0.1 ppm, respectively.

* CBTS's Response #7d:

As indicated above, the deficiencies outlined in Conclusions #5, 6, and 7b are considered to be resolved.

* Other Considerations:

1. Additional Formulation - Tilt Gel:

The petitioner is adding the proposed use of Tilt Gel (EPA Reg. No. 100-737) to this petition claiming that the proposed use directions are identical to those proposed for Tilt (EPA Reg. No. 100-618).

* CBTS's Response:

Both Tilt and Tilt Gel contain 41.8% propiconazole. Tilt is available as an emulsifiable concentrate designed to be dissolved

in water prior to application and Tilt Gel is available in water soluble packets also designed to dissolve in water. Since both formulations are designed to be dissolved in water prior to application and are applied to the emerging flag leaf or at an earlier stage, data can be translated among these formulations.

2. Feeding Restrictions for Oat Hay:

a. Tolerances for Oat Hay: Residue data have not been submitted for oat hay in this petition. CBTS no longer considers feeding restrictions practical for this commodity [Table II (June 1994)]. The petitioner has two options regarding this issue: (1) propose a tolerance of 30 ppm for oat hay (based on a dry down factor of 3X for oat forage) or (2) place a feeding restriction for oat hay on the Tilt labels while residue data are being generated. In the latter case the tolerances for oat grain, forage, and straw should be established with an expiration date with the permanent tolerance contingent upon submission of adequate data for oat hay.

b. Meat/milk Tolerances: Feeding studies with propiconazole have been discussed in previous petitions. PP4F3074 (Memorandum by A. Smith dated July 12, 1984) discusses feeding studies in which lactating cows were fed parent compound in the daily diet at levels of 15, 75, and 150 ppm for up to 28 days. The samples were analyzed for total residues of the parent compound. For milk, no residues were noted at the 15 ppm feeding level. Total residues ranging from <0.01 to 0.08 ppm were noted at the 75 ppm feeding level and plateaued at 0.08 ppm on day 7. At the 150 ppm feeding level, total residues ranged from <0.01 to 0.11 ppm and plateaued at 0.11 ppm on day 14. No residues of the parent compound were reported for any feeding level.

Residues were found in all tissues (tenderloin, round, kidney, liver, omental fat, perirenal fat) and at all feeding levels. Maximum residues were noted in the kidney and liver. The reported residues for all tissues are summarized as follows.

Tissue	Feeding Level *(ppm)*		
	15	75	150
Kidney	0.56-0.63	3.0-4.7	5.0-6.5
Liver	0.50-0.81	2.7-4.3	4.6-5.6
Fat	<0.05[1]	0.07-0.23	0.13-0.26
Round	<0.05[1]	0.05-0.11	0.11-0.18
Tenderloin	<0.05[1]	<0.05-0.08	<0.09-0.13

1 Non-detectable

A plausible **ruminants (cattle, dairy)** exposure analysis is as follows.

Feed Item	**Tolerance** *(ppm)*	**% in Diet**	**% Dry Matter**	**Exposure**[1] *(ppm)*
Oats hay	30	35	90	11.7
Grass hay	40	20	88	9.1
Grass silage	0.5	20	40	0.3

1 **Total exposure = 21.1 ppm**, calculated as Σ[(Tol)(%Diet)÷(%DM)]

This is a 40 CFR §180.6(a)(1) with respect to secondary residues in meat, milk, and eggs.

According to the exposure analysis and the available feeding data, the established tolerances for cattle, goats, hogs, horses, and sheep fat, kidney, liver, meat, and meat by-products (excluding kidney and liver) are adequate for the proposed use of propiconazole in/on oats.

cc: MIRodriguez, PP#2F04086, Reading File, Circulation.
RDI: RBPerfetti/RALoranger (3-15-95)
MIRodriguez: Draft (3-10-1995), Edited (3-15-1995).
Mail Code 7509C; Tel (703)-305-6710; CM #2, Rm 804-T.

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

JUL 20 1993

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Memorandum

Subject: PP#2F4086. Propiconazole (**Tilt**) in/on Oat Grain and Straw. Evaluation of Analytical Method and Residue Data. CBTS# 9325, 9603. MRID# 421829-01. DP Barcode# D174248, D175989.

From: Robert Lascola, Chemist
Chemistry Branch I - Tolerance Support
Tolerance Petition Section III
Health Effects Division (H7509C)

Robert Lascola

Through: Debra F. Edwards, Branch Chief
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

Debra Edwards
7/19/93

To: Sidney Jackson/Susan Lewis (PM21)
Fungicide/Herbicide Branch
Registration Division (H7505C)

CIBA-GEIGY Corporation, Agricultural Division, has submitted a petition proposing tolerances for the fungicide propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-1*H*-1,2,4-triazole), and its metabolites determined as 2,4-dichlorobenzoic acid, on oat grain (0.1 ppm) and straw (1.0 ppm). Permanent tolerances have been established under 40 CFR §180.434 for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent compound) on the following raw agricultural and animal commodities:

Bananas	0.2 ppm	Rice, straw	3.0 ppm
Barley, grain	0.1	Rye, grain	0.1
Barley, straw	1.5	Rye, straw	1.5
Pecans	0.1	Wheat, grain	0.1
Rice, grain	0.1	Wheat, straw	1.5
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Animal*, fat	0.1	Animal*, meat	0.1
Animal*, mbyp (except liver and kidney)	0.1	Eggs	0.1
		Milk	0.05
Poultry, fat	0.1	Poultry, meat	0.1
Poultry, mbyp (except liver and kidney)	0.1	Poultry, liver & kidney	0.2

*Animal = cattle, goats, hogs, horses, and sheep.

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Temporary tolerances, extended through January 31, 1994 (telecon, S. Jackson, RD), have also been established for the following commodities: kidney and liver of cattle, goats, hogs, horses, and sheep (2.0 ppm each), grass forage (0.5 ppm), grass hay (5.0 ppm), and grass screenings (10.0 ppm). There are no food or feed additive tolerances currently established for propiconazole.

Propiconazole is a List C chemical. The Phase 4 review, completed 4/30/92, identified numerous reregistration data gaps, including the nature of the residue in plants and ruminants, storage stability, analytical method (plants), and residue data for several crops. Where possible, we will allow the petitioner to address these concerns in the reregistration process.

There are pending tolerances for corn, celery, pineapples, and legume vegetables (PP#8F3674), grass seed screenings, straw, and forage (PP#1F3974), peanuts (PP#8F3654), and mint (PP#2E4037). CBRS has recently registered no objections to a Section 18 registration allowing use of propiconazole on sweet corn and seed corn (92-FL-10, D. McNeilly, 7/27/92).

Conclusions

1a. CBTS is willing to accept previously submitted plant metabolism data in support of this petition, based on the existing tolerances for other cereal crops and the low tolerance levels proposed for oat grain and straw. The residues of concern are the parent compound, propiconazole, and its metabolites determined as 2,4-dichlorobenzoic acid.

1b. The Phase 4 Review for propiconazole has identified a data gap for plant metabolism, proposing additional radiolabeling studies for wheat, bananas, and pecans. CBTS concludes that this data gap can be addressed in the reregistration process.

2a. CBTS concludes that the nature of the residue in animals is understood, based on studies submitted with PP#4F3007. The residues of concern are the parent compound, propiconazole, and its metabolites determined as 2,4-dichlorobenzoic acid.

2b. CBTS has recently concluded (PP#1F3974) that the nature of the residue for both ruminants and poultry is not understood. However, this determination was made assuming an increased dietary burden due to the tolerances proposed in that petition. The tolerances proposed in this petition will not add to the dietary burden, since the commodities, oat grain and straw, would only replace other feed items for which identical tolerances have already been established. Therefore, the concerns about animal metabolism expressed in that petition do not apply to this petition.

3. The proposed analytical method for detection of propiconazole in oat grain and straw, AG-454A, has been shown to adequately recover the pesticide and its metabolites as a 2,4-dichlorobenzoic acid methyl ester derivative. The limit of detection is 0.05 ppm (propiconazole equivalents). Both AG-454A and the method for animal commodities, AG-517, have been successfully validated by the Agency's Analytical Chemistry Section/BEAD.

4. Product chemistry data has been previously submitted and reviewed by the Agency. All

requirements for this section have been met.

5. The petitioner has not submitted adequate storage stability data. Previously submitted data for peanuts and soybeans can not be translated to the oat grain and straw samples. In PP#1F3974, the petitioner indicated that a storage stability study for grass straw and forage is nearing completion. CBTS could translate this data to oats; however, to assure timely resolution of this deficiency, the petitioner should conduct storage stability studies on oats or another cereal grain crop.

6. CBTS has found the following deficiencies in the proposed labeling. The petitioner must remove the uses of thiabendazole and thiophanate-methyl on barley, rye, and oats, as there are no tolerances for those chemicals on those commodities. Also, the petitioner should clarify that only one application of propiconazole at 50 g ai/A is allowed per season for control of foot rot. The petitioner should also express the time of applications as days before harvest as well as by plant growth stage, and indicate the amount and kind of solvent used to dilute the product (if any is used).

7a. The submitted data supports the proposed tolerances of 0.1 ppm in oat grain and 1.0 ppm in oat straw (however, see Conclusion 7c). Observed residues in grain treated at the 1X rate were $\leq$0.06 ppm in all cases. The highest observed residue in straw from 1X-rate trials was 0.62 ppm.

7b. The petitioner has also submitted residue data on oat forage. This data would support a tolerance of 10.0 ppm, if the petitioner wishes to remove the label restriction against feeding oat forage. In this case, appropriately revised Sections B and F should be submitted to the Agency.

7c. CBTS concludes that no food or feed additive tolerances are necessary for oat processing fractions. The two fractions in which propiconazole seemed to concentrate at the 5X treatment rate, hulls and feed oats, did not show any concentration at the 3X treatment rate. Also, in the 5X treatment rate trials, the amount by which the residue levels for those fractions exceeded the levels for whole oats, 0.03 and 0.02 ppm, are within the error of the analytical method. Therefore, there is no evidence that propoiconazole residues concentrate in oat fractions.

7d. CBTS cannot recommend for appropriate tolerance levels for propiconazole in oats grain and straw until storage stability (Conclusion 5) and proposed labeling (Conclusion 6) deficiencies have been corrected.

8. Since recent concerns of an increased dietary burden for animals (see Conclusion 2b) do not apply to this petition, CBTS concludes that no further animal feeding data needs to be submitted for this petition. Adequate animal tissue, milk, and egg tolerances exist to cover residues in those commodities incurred from the proposed use.

9a. There are no Canadian or Mexican tolerances for propiconazole in oat grain or straw; therefore, no compatibility problems are expected. There is a Codex tolerance, for parent only, on oat grain at 0.05 ppm. Due to the data gap in plant metabolism

identified in the Phase 4 review, CBTS can not discuss at this time the feasibility of harmonization of the U.S. and Codex tolerance expressions.

9b. No Craven data are associated with this petition.

Recommendations

CBTS recommends against the proposed tolerances for propiconazole of 0.1 ppm in oat grain and 1.0 ppm in oat straw for the reasons outlined in Conclusions 5, 6, and 7d.

Note to PM: Please be aware of our Conclusion 7b regarding a potential tolerance for oat forage.

Detailed Considerations

Manufacturing Procedure

The product chemistry data for propiconazole has been reviewed previously by the Agency (W.T. Chin memo of 5/20/88). There are no outstanding deficiencies associated with this section. The TGAi is 88% pure; its impurities are not expected to produce a residue problem. The proposed formulation, **Tilt**, contains 3.6 lbs ai/gallon liquid concentrate, or 47.6% TGAI by weight.

Proposed Use

Tilt 3.6E is proposed for use on cereal grains (wheat, barley, rye, and oats) for control of rusts, powdery mildew, leaf and glume blotch, tan spot, Helminthosporium leaf blight, barley scald, and net blotch. One application of 50 g ai/A may be made per season. This application may be made up to Feekes growth stage 8, when the ligule of the flag leaf emerges. The timing of this application is approximately 5-7 weeks prior to harvest,[1] with the range of PHIs depending on temperature. The petitioner should confirm this estimate and indicate the appropriate time intervals on the label. The petitioner should also indicate the amount and kind of solvent used to dilute the product (if any is used).

Tilt, in combination with the fungicides **Benlate** (benomyl), **Mertect** (thiabendazole), and **Topsin M** (thiophanate-methyl), may also be applied for control of foot rot. The proposed application rate is 50 g ai/A (plus half-rates of the other fungicides), with application at tillering but before elongation has occurred. CBTS notes that there are tolerances for benomyl on wheat, barley, rye, and oats (40 CFR §180.294). However, for thiabendazole (§180.242) and thiophanate-methyl (§180.371), there are only tolerances for wheat. Therefore, the petitioner must remove from the label the inferred uses of thiabendazole and thiophanate-methyl on barley,

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[1]. From 11/18/92 telecon with Prof. D. Peterson, Univ. of Wisconsin, Dept. of Agronomy (608) 262-4482.

rye, and oats.

With regards to the foot rot use, it is implied, but not clearly stated, that only one application per season is allowed. The petitioner should explicitly mention this restriction in a revised Section B.

Restrictions include, "Do not graze or feed livestock treated forage or cut the green crop for hay or silage. After harvest, the straw may be used for bedding or feed." Oat forage is considered to be under grower control. Thus, this restriction is valid.

To summarize, CBTS has found the following deficiencies in the proposed labeling. The petitioner must remove the uses of thiabendazole and thiophanate-methyl on barley, rye, and oats, as there are no tolerances for those chemicals on those commodities. Also, the petitioner should clarify that only one application of propiconazole at 50 g ai/A is allowed per season for control of foot rot. The petitioner should also express the time of applications as days before harvest as well as by plant growth stage, and indicate the amount and kind of solvent used to dilute the product (if any is used).

Nature of the Residue - Plants

Plant metabolism data were not submitted with this petition. The Phase 4 Review (4/30/92) has identified a data gap in this area, stating,

Phenyl-^{14}C-propiconazole should be applied to wheat, bananas, and pecans reflecting the currently registered use patterns. The specific activity and/or application rate should be high enough to allow for adequate identification of the metabolites/degradates. If metabolism is similar in these three unrelated crops then only these three must be tested. The plant material from the metabolism studies should be tested using the data collection method(s) and enforcement analytical method(s).

CBTS concludes that this data gap can be addressed in the reregistration process. Based on the existing tolerances for cereal crops, and the low tolerance levels proposed for oat grain and straw, CBTS is willing to accept previously submitted plant metabolism data in support of this petition. Therefore, the residues of concern are the parent compound, propiconazole, and its metabolites determined as 2,4-dichlorobenzoic acid.

Full reviews of those plant metabolism studies can be found in PP#4F3007, A. Smith memo of 5/15/84. A summary of the wheat metabolism is presented as relevant to the proposed oats tolerances. Two separate studies were performed, one with ^{14}C-triazole label, and one with ^{14}C-phenyl label. Each was applied at the rate of 0.11 lb ai/A. Triazole samples were harvested 49 days, and phenyl samples 41 days, after application. Total radioactivity was measured by combustion analysis with LSC. Residue components were characterized and quantitated by GLC, HPLC, and electrophoresis. Conjugated components were released by hydrolysis with HCl. In both cases, the parent compound was absorbed, metabolized, and translocated to the grain. Residues were higher for the triazole label, with 54% of the residue identified as the alanine conjugate of 1,2,4-triazole (CGA-131013). No parent was observed in the grain. In straw, the primary components were parent and the free and bound forms of four bridge-intact

metabolites, all hydroxylated on the n-propyl side chain of the dioxolane ring.

Nature of the Residue - Animals

Animal metabolism data was not submitted with this petition. Although tolerances exist for animal products, CBTS has recently concluded (PP#1F3974, S. Willett, 6/11/91) that the nature of the residue for both ruminants and poultry is not understood. In previous ruminant metabolism studies (reviewed in PP#4F3007, A. Smith, 5/15/84), some low levels of activity were not characterized. At that time, the anticipated dietary burden was small, as the only existing tolerances were at low levels. The low activity levels found in those studies may be significant now due to several proposed tolerances which will increase the exposure of cattle and poultry. These petitions include 9F3706 and 1F3974 (grass seed screenings), 8F3654 (peanuts), and 8F3674 (corn). The proposed tolerances for the grass and corn feed items are:

grass seed screenings	70 ppm	corn grain	0.1 ppm
grass straw	40 ppm	corn forage	10.0 ppm
grass forage	2 ppm	corn fodder	10.0 ppm

New ruminant (MRID# 418233-01) and poultry (418233-02) metabolism studies were reviewed in connection with PP#1F3974. CBTS withheld its decision on the adequacy of both metabolism studies until appropriate tolerances were determined for grass seed screenings, straw and forage, and corn grain, forage, and fodder, and a subsequently better estimate of the dietary burden to cattle and poultry could be made. Additional characterization of residues in cattle liver and kidney may be necessary if the residue levels in the feed items approach those used in the metabolism studies (67 to 90 ppm). The poultry metabolism study was found to be generally acceptable, again pending the final decisions on the grass seed and corn tolerances. However, for both studies, no details on sample handling and length of storage were supplied, and no data from storage stability studies on animal commodities were submitted or referenced.

The proposed tolerance for oat grain, 0.1 ppm, is identical to the established tolerances for barley, rice, rye, and wheat grains. The proposed oat straw tolerance, 1.0 ppm, is less than the existing tolerances for the straw of those other cereal crops. It is also likely that the use of oat grain and straw in animal feed would **replace** the use of other cereal crop feed items. Therefore, the establishment of this tolerance would not add to the **current** dietary burden to farm animals. Thus, the concerns over the feeding levels of the recent metabolism studies do not apply in this case.

CBTS concludes that the nature of the residue in animals is understood, based on studies submitted with PP#4F3007. The residues of concern are the parent compound, propiconazole, and its metabolites determined as 2,4-dichlorobenzoic acid.

Analytical Method

Analtical methodologies for the determination of propiconazole and its metabolites in plant and animal commodities (Ciba-Geigy Analytical Methods AG-454A and AG-517, respectively) have

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been successfully validated by the Agency's Analytical Chemistry Section and have been approved for publication in PAM II for enforcement purposes (letter, S. Malak to A. Marcotte (FDA), 5/28/87). The petitioner has included recovery data for oat grain, straw, forage, and processed products, which are summarized in Table 1. Adequate chromatograms have also been submitted. The apparent level of detection for all oat products is 0.05 ppm (propiconazole equivalents). CBTS concludes that the proposed analytical methods are adequate for data collection purposes. We note, however, that recoveries from straw are marginal.

In the method, crop samples are extracted by refluxing with 20% concentrated NH_4OH/MeOH for one hour. An aliquot taken for analysis is concentrated and refluxed with $KMnO_3$ in NaOH for 1h 15min. The acidified extract is then partitioned with 10% diethyl ether/hexane. The organic phase is evaporated to dryness and derivatized with diazomethane. The derivative, 2,4-dichlorobenzoic acid methyl ester is cleaned up using an acidic alumina Sep-Pak. Residues are determined by capillary GC/electron capture detection.

The Phase 4 review indicated that new validation studies for AG-454A are necessary for recovery from bananas, and that a new method for all commodities may be necessary may be necessary if new metabolites are found in the required plant and/or animal metabolism studies. The Phase 4 review has also requested that the petitioner submit information indicating why appropriate methylating agents cannot be substituted for diazomethane. These concerns can be addressed in the reregistration process.

Table 1. Procedural Recoveries for Propiconazole from Oat Products Using AG-454A.

	Recoveries (%)			
Spike (ppm)	Grain	Straw	Forage	Processed Products[1]
0.05	109,65,72,67	58,79,59	96,87	65[a],88[c],(89,81,86)[d], 85[e],86[g],63[i]
0.10	69,84,72	77	---	77[f],82[h]
0.20	70,71,73	62,57,64	---	61[b]
0.50	79,87	55,66,54,50	66,54,69	(102,85,86)[e]
1.0	84,85	81	72,73,70	138[i]
2.0	---	65	87	
≥5.0	---	67	78,72,74[2],75, 82,66,74	
Average	77.6 ± 11.6	63.8 ± 9.6	74.7 ± 9.9	

1 - Processed products include: a- whole oats, b- hulls, c- rolled oats, d- bran, e-flour, f-light impurities, g- feed oats, h- groats, i- fines (oat feed).

2 - All controls less than 0.05 ppm except as noted, which was 0.25 ppm (spike of 5.0 ppm).

Multiresidue methodology data have been sent to the FDA (4/28/87). Recovery of propiconazole via FDA Multiresidue Protocol D (PAM II 232.4) is complete while recovery of

propiconazole metabolites (CGA-91305, CGA-118244, and 1,2,4-triazole) via this method is variable.

Storage Stability

Field samples in this petition were stored frozen (-20°C) for 5-19 months. The petitioner has not submitted any storage stability data. Instead, data from soybean and peanut commodity studies was referenced. This data was previously reviewed in PP#4F3007. The data for soybeans indicate no significant degradation of residues for 4-6 months of frozen storage. However, the Phase 4 review has indicated that the storage stability data for peanut fodder, shells, and nutmeat are completely inadequate, and has concluded that new studies must be conducted on all crops and processed products for which a field trial and/or processing study has been or will be conducted, as well as representative livestock studies.

CBTS concludes that the soybean storage stability study does not support this petition. We are generally reluctant to translate storage stability data between crop groupings, and the duration of the soybean storage study is too short to support the field trial data in this petition. In PP#1F3974, the petitioner has indicated that a storage stability study for weathered residues of propiconazole in grass straw and forage has been initiated and will run through December 1992. (In that petition, grass samples were stored frozen for a maximum of 16 months.) CBTS **may** decide that the grass straw and forage storage stability study results would support the oat straw and grain data. However, to assure timely resolution of this deficiency, the petitioner should conduct storage stability studies on oats (or another cereal grain) reflecting the storage intervals in the residue data.

Residue Data

The petitioner has conducted both residue and processing trials for propiconazole in oats. The results of these trials are contained in MRID# 421829-01 (Ciba-Geigy Project No. ABR-89012). Eleven trials were conducted, one each in the following states: MN, NE, CA, IL, OR, LA, ND, SD, IA, NY, and WI. This group of states includes all major oats producing states (i.e. >5% of US production) and in total represents 73% of 1990 US production (1991 Agricultural Statistics). Geographical representation is adequate. Propiconazole (**Tilt 3.6E**) was applied to oats one time at rates of 50, 100, 150, or 250 lbs ai/A (1X, 2X, 3X, or 5X the proposed rate). Dilution of **Tilt** in water ranged from 19 to 44 gallons/acre. PHIs ranged from 35 to 80 days. Oats grain, forage, and straw samples were collected from each site, stored frozen for 5-19 months, and analysed using Ciba-Geigy Method No. AG-454A. The limit of detection for grain and straw is 0.05 ppm. Analytical data is supplemented with sample chromatograms. Detailed results are presented in Table 2. Control samples in most cases (see Table 2) contained <0.05 ppm residues.

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Table 2. Propiconazole Residues in Oats Grain, Forage, and Straw (from MRID# 421829-01).

				Residues (ppm)[2]		
Site	Rate[1]	GPA	PHI (days)	Grain	Forage	Straw
MN	1X	20	41	<0.05, <0.05	2.3, 2.6	(0.15, 0.14), (0.22, 0.19)
NE	1X	20	40	<0.05, <0.05	3.9, 3.7	0.49, 0.35
CA	1X 2X	44	80	<0.05, <0.05 <0.05	4.7, 3.9 8.1	0.33, 0.29 0.57
IL	1X 2X	20	35	<0.05, <0.05 0.08	2.2, 4.0 9.5	0.20, 0.56 1.1
OR	1X	24.2	78	<0.05, <0.05	1.3, 1.2	0.16, 0.12
LA	1X	26.3	75	<0.05, <0.05	2.4, 4.8	(0.28, 0.29), (0.30, 0.31)
ND	1X	20	46	(0.06, 0.06), (<0.05, <0.05)	(6.3, 4.5)[3], (5.8, 5.9)	0.13, 0.11
SD	1X 2X	19	50	(0.05, <0.05), (<0.05, <0.05) (0.08, 0.07)	(5.8, 4.9), (7.5, 5.9) (23, 19)	0.19, 0.19 0.58
IA	1X 3X 5X	20	49	<0.05 <0.05 <0.05	3.3, 2.1 9.8 16.	0.58, 0.44 2.0 3.4
NY	1X 2X	30	41	<0.05, <0.05 <0.05	2.5, 2.5 5.6	(0.53, 0.56), (0.43, 0.46) (1.1, 1.1)
WI	1X 3X 5X	27.36	63	<0.05, <0.05 0.07, 0.06 0.16, 0.09	2.1, 2.4 7.3 16.	0.59, 0.62 2.0 8.9

1 - 1X = 50 g ai/A.
2 - Numbers in parentheses represent duplicate analyses of the same sample. Residues were detected as 2,4-dichlorobenzoic acid and converted to propiconazole equivalents.
3 - ND forage control sample showed 0.27 and 0.25 ppm in two analyses.

The petitioner has not proposed any tolerances for processed oat fractions. In support of this, a processing study was also conducted with samples from the WI trial. Processing products include whole oats, hulls, rolled oats, flour, fines, feed oats, groats, bran, and light impurities. Also included is a processing flowchart for oat fractions, which can be found in Appendix 2. Processing took place at Texas A&M University, following SOP No. 8.18 (included as an attachment in the petitioner's report). The methods used are consistent with industrial processing procedures. Details of the analysis are presented in Table 3.

Table 3. Propiconazole Residues in Processed Oat Fractions (from MRID# 421829-01).[1]			
	Residues (ppm)[2]		
Substrate	1X Rate	3X Rate	5X Rate
whole oats	<0.05	0.09	0.14
hulls	<0.05	0.09	0.17
rolled oats	<0.05	<0.05	0.09
flour	<0.05	0.05	0.07
fines (oat feed)	<0.05	<0.05	<0.05
bran[3]	<0.05, <0.05, <0.05	0.08, 0.06, 0.11	<0.05, <0.05, 0.06
feed oats	<0.05	0.06	0.16
groats	<0.05	<0.05	0.09
light impurities[4]	<0.05	0.18	0.26

1 - Details of the WI residue trial from which these samples were taken are in Table 2.
2 - Detected as 2,4-dichlorobenzoic acid and converted to propiconazole equivalents.
3 - Residues in control samples were 0.13, 0.09, and 0.15 ppm (triple analysis). See text for discussion. Residues in all other control samples were <0.05 ppm.
4 - The petitioner notes, "The light impurities fraction samples contained oat straw, which is atypical of this fraction when obtained from commerical processing. These samples, therefore, do not represent a commercially produced light impurities fraction."

As indicated in Footnote 3 of Table 2, residues in control samples processed for bran were higher than residues in treated bran. The petitioner states, "Control bran samples and the 5X bran sample appear to be switched. Samples were realiquotted from original extract and reanalyzed, then reextracted and reanalyzed. Samples were analyzed as labeled by the commercial processor."

The petitioner did not undertake any analysis of grain dust. The petitioner states,

The Agency's current policy on the necessity of grain dust data is outlined in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance, December 24, 1989, page E-11. It states that "The grain dust data are needed only in those cases in which detectable, primarily surface residues are found on the grain. Early season herbicide uses usually result in low residues that would not be concentrated on the grain surface. Therefore, grain dust data would seldom be required in those cases. At the other extreme, postharvest treatments of stored grains virtually always trigger the need for grain dust data. Late season foliar uses to exposed grains such as wheat would also usually require such data." The use of propoiconazole in oats involves no application to exposed grain, and would not, therefore, be expected to trigger the requirement of grain dust data. This conclusion is further supported by the lack of detectable residues in most of the grain samples.

CBTS Comments: The submitted data supports the proposed tolerances of 0.1 ppm in oat grain and 1.0 ppm in oat straw. (However, see below.) Observed residues in grain treated at the 1X rate were $\leq$0.06 ppm in all cases. The highest observed residue in straw from 1X-rate trials was 0.62 ppm. Seven of the eleven trials were conducted at PHIs which correspond to the range associated with the application for control of rusts, powdery mildew, etc. The remaining four

trials are at PHI's appropriate for the use for control of foot rot. (See the **Proposed Use** section.)

As indicated in the processing scheme in Appendix 2, processed oat products are created from whole oats. Therefore, whole oats are the commodity to which the processed products must be compared in order to determine the concentration of residues. At the 1X application rate, no residues are detected in whole oats or in the processed commodities. No concentration of residues are observed at the 3X rate, except for light impurities (see below). At the 5X rate, concentration factors of 1.2X were found in hulls, and 1.1X in feed oats; residues in all other processed fractions did not concentrate (except for light impurities). Residues in bran samples were estimated by averaging the results of the three replicate analyses for each treatment rate.

Note that the petitioner states that the light impurities samples were contaminated with straw, contrary to commercial practice. This is a reasonable explanation of the high residues found in that fraction. Also, the Agency does not set tolerances on the light impurities fraction. Therefore, neither a food nor a feed additive tolerance is necessary for this commodity.

CBTS concludes that no food or feed additive tolerances are necessary for oat processing fractions. The two fractions in which propiconazole seemed to concentrate at the 5X treatment rate, hulls and feed oats, did not show any concentration at the 3X treatment rate. Also, in the 5X treatment rate trials, the amount by which the residue levels for those fractions exceeded the levels for whole oats, 0.03 and 0.02 ppm, are within the error of the analytical method. Therefore, there is no evidence that propoiconazole residues concentrate in oat fractions.

Note, however, that CBTS can not recommend for appropriate tolerance levels for propiconazole in oats grain and straw until storage stability and proposed labeling deficiencies have been corrected.

Meat, Milk, Poultry, and Eggs

No information on animal feeding studies has been submitted with this petition. CBTS has previously reviewed (PP#4F3074/4F3007/4E3026, S. Malak memo of 5/14/87) and accepted livestock and poultry feeding studies. Since recent concerns of an increased dietary burden for animals (see **Nature of the Residue - Animals**) do not apply to this petition, CBTS concludes that no further animal feeding data needs to be submitted for this petition. Adequate animal tissue, milk, and egg tolerances exist to cover residues in those commodities incurred from the proposed use.

A summary of those studies is presented below. Lactating cows were fed propiconazole at levels of 15, 75, and 150 ppm for periods of 14, 21, or 28 days. Milk samples were collected daily and the animals sacrificed at 14, 21, and 28 days during the study period. Laying hens were fed propiconazole in their daily ration at levels of 7.5, 37.5, and 75 ppm for 14, 21, and 28 days. Egg samples were collected daily and chickens were sacrificed at weekly intervals. All samples were analyzed using method AG-359, which determines propiconazole and its metabolites containing the 2,4-dichlorophenyl moiety. This method was found adequate for the purposes of data collection. Method sensitivity was reported at 0.01 ppm for milk and kidney,

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0.10 ppm for liver, and 0.05 ppm for other tissues. The following residue levels were found:

Table 4. Propiconazole Residues in Cattle and Poultry Commodities.

Feeding Length	14 days			21 days			28 days		
Cattle	**15**	**75**	**150**	**15**	**75**	**150**	**15**	**75**	**150**
Tissues	<.05	0.11	0.18	<.05	0.08	0.13	<.05	0.05	0.11
Kidney	0.61	3.04	6.48	0.56	4.68	5.0	0.63	3.68	5.5
Liver	0.5	4.0	4.6	0.81	4.3	5.3	0.57	2.7	5.6
Fat	<.05	0.23	0.26	<.05	0.15	0.19	<.05	0.08	0.17
Poultry	**7.5**	**37.5**	**75**	**7.5**	**37.5**	**75**	**7.5**	**37.5**	**75**
Tissues	<.05	---	---	<.05	<.05	0.07	<.05	<.05	0.06
Liver	<0.1	0.1	0.47	---	0.08	0.39	<0.1	0.16	0.3
Fat	---	<.05	0.11	---	<.05	0.06	---	<.05	0.05

In milk, no detectable residues were found at the 15 ppm feeding level (<0.01 ppm). A maximum of 0.1 ppm and 0.11 ppm, respectively, were found at the 75 and 150 ppm feeding levels. In eggs, no residues were found at the lowest feeding level. At the 37.5 ppm level, residues did not appear until Day 3, peaked at 0.18 ppm on Day 14, and decreased to 0.06 ppm by Day 28. A similar response was seen for the highest feeding level, with appearance at Day 3, peaking on Day 21 at 0.37 ppm, and decrease to 0.22 ppm by Day 28.

Other Considerations

There are no Canadian or Mexican tolerances for propiconazole in oat grain or straw; therefore, no compatibility problems are expected. There is a Codex tolerance, for parent only, on oat grain at 0.05 ppm. Due to the data gap in plant metabolism identified in the Phase 4 review, CBTS can not discuss at this time the feasibility of harmonization of the U.S. and Codex tolerance expressions.

No Craven data are associated with this petition.

cc: R. Lascola, SF, RF, Circulation(7), D. Edwards, PP#2F4086,
J. Fleuchaus, Pesticides and Toxic Substances Division (LE-132P)

H7509C:CBTS:RLascola/rjl:CM#2:Rm805B:305-7478:11/18/92.
RDI: P.V.Errico:7/13/93; R.Loranger:7/13/93.
◙:Disk\4086.TXT

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8/27/92

Attachment: Page 1 of 1

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL propiconazole*

CODEX NO. 160

CODEX STATUS:

[ ] No Codex Proposal Step 6 or Above

Residue (if Step 8): propiconazole

Crop(s)	Limit (mg/kg)
Oats grain	0.05**

PROPOSED U.S. TOLERANCES:

Petition No. 2F4086

DEB Reviewer R Lascola

Residue: parent and its metabolites expressed as 2,4-dichlorobenzoic acid

Crop(s)	Limit (mg/kg)
oats, grain	0.1
, straw	1.0

CANADIAN LIMITS:

[✓] No Canadian Limit

Residue:

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

[✓] No Mexican Limit

Residue:

Crop(s)	Limit (mg/kg)

NOTES

Form Revised 1989

* (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-1H-1,2,4-triazole)

** at or about the limit of determination

B4

Lascar, Glenn H TP53

[PF-564; FRL-4066-2]

Pesticide Tolerance Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions (PP) and food and feed additive petitions (FAP) proposing the establishment of regulations for residues of certain pesticide chemicals in or on certain agricultural commodities. It also announces two amended petitions and a corrected petition.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1128, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked 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

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may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1128 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, contact the PM named in each petition at the following office location/ telephone number:

Product Manager	Office location/ telephone number	Address
George LaRocca (PM-13).	Rm. 202, CM #2, 703-557-2400.	1921 Jefferson Davis Hwy., Arlington, VA.
Phil Hutton (PM-18).	Rm. 213, CM #2, 703-305-7690.	Do.
Dennis Edwards (PM-19).	Rm. 207, CM #2, 703-305-5386.	Do.
Susan Lewis (PM-21).	Rm. 227, CM #2, 703-305-6900.	Do.
Cynthia Giles-Parker (PM-22).	Rm. 229, CM #2, 703-305-5540.	Do.
Joanne Miller (PM-23).	Rm. 237, CM #2, 703-305-7830.	Do.
Robert Taylor (PM-25).	Rm. 241, CM #2, 703-305-6800.	Do.
Hoyt Jamerson (PM-43).	Rm. 716C, CM #2, 703-305-5310.	Do.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions and food/ feed additive petitions as follows proposing the establishment and/or amendment of regulations for regulations for residues of certain pesticide chemicals in or on various agricultural commodities.

Initial Filings

1. *PP 2F4072.* Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419-8300, proposes to amend 40 CFR 180.408 by establishing a regulation to permit combined residues of the fungicide metalaxyl (N-(2,6-dimethylphenyl)-N-(methoxyacetyl)aniline methyl ester) and its metabolites containing the 2,6-dimethylaniline moiety, and N-(2-hydroxymethyl-6-methylphenyl)-N-methoxyacetyl) aniline methyl ester, each expressed as metalaxyl equivalents in or on brassica (cole) leafy vegetable crop grouping at 5.0 parts per million (ppm). (PM-21)

2. *PP 2F4075.* BASF Corp., Agricultural Chemicals, P.O. Box 13528, Research Triangle Park, NC 27709-3528, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on rice grain at 0.1 ppm and rice straw at 0.5 ppm. (PM-25)

3. *PP 2F4076.* EcoScience Corp., 85 North Whitney St., P.O. Box 300, Amherst, MA 01004, proposes to amend 40 CFR part 180 by establishing a regulation for permanent exemption from the requirement of a tolerance for *Metarhizium anisopliae* in or on all raw agricultural commodities. (PM-18)

4. *PP2F4077.* FMC Corp., Agricultural Chemicals Group, 1735 Market St., Philadelphia, PA 19103, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of 2-(2-chlorophenyl) ethyl-4,4-dimethyl-3-isoxazolidinone in or on cottonseed at 0.05 ppm. (PM-25)

5. *PP 2F4078.* FMC Corp., Agricultural Chemicals Group, 1735 Market St., Philadelphia, PA 19103, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of (±)*cis,trans*-3-(2,2-dichloro-ethenyl)-2,2-dimethylcyclopropane carboxylate cypermethrin and its metabolites dichlorovinyl acid (DCVA) and *m*-phenoxybenzoic acid (MPB Acid) in or on sorghum grain at 3.0 ppm, sorghum fodder/forage at 12.0 ppm, sorghum, green and chopped/silage at 6.0 ppm, and sorghum hay at 31.0 ppm. (PM-13)

6. *PP 2F4081.* Monsanto Co., Suite 1100, 700 14th St., NW., Washington, DC 20005, proposes to amend 40 CFR 180.364 by establishing a regulation to permit residues of glyphosate (N-(phosphonomethyl) glycine) and its metabolite aminomethylphosphonic acid resulting from the application of the isopropylamine salt of glyphosate and/ or the monoammonium salt of glyphosate in or on almond hulls at 25 ppm and tree nut crops at 1.0 ppm. (PM-25)

7. *PP 2F4082.* McLaughlin Gormley King Co., 8810 Tenth Ave. North, Minneapolis, MN 55427-4372, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of insecticide (S)-cyano(3-phenoxyphenyl)methyl-(S)-4-chloro-alpha-(1-methylethyl)benzeneacetate in or on cocoa at 1.0 ppm. (PM-13)

8. *PP 2F4083.* Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419-8300, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of the fungicide propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole)], and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in or on oat grain at 0.1 ppm, and oat straw at 1.0 ppm. (PM-21)

9. *PP 2F4089.* Espro, Inc., 1015 15th St., NW., Suite 500, Washington, DC 20005, proposes to amend 40 CFR part 180, by establishing a regulation exempting acal from the requirement of a tolerance. (PM-18)

10. *PP 2F4090.* Espro, Inc., 1015 15th St., NW., Suite 500, Washington, DC 20005, proposes to amend 40 CFR part 180 by establishing a regulation to exempt cydx from requirement of a tolerance. (PM-18)

11. *PP 2F4091.* E. I. du Pont de Nemours Co., Inc., Walker's Mill, Barley Mill Plaza, P.O. Box 80038, Wilmington, DE 19880-0038, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of the insecticide methomyl (S-methyl N-[methylcarbamoyl] thioacetimidate in or on sugarbeet tops at 1.0 ppm. (PM-19)

12. *PP 2F4097.* Jellinek, Schwartz, Connolly, Freshman, Inc., 1015 15th St., NW., Washington, DC 20005, proposes to amend 40 CFR part 180 by establishing a regulation to permit the residues of pentachloronitrobenzene (PCNB) in or on potatoes at 2.0 ppm. (PM-21)

13. *PP 2F4098.* Versar, Inc., RiskFocus Division, 6850 Versar Center, Springfield, VA 22151, proposes to amend 40 CFR part 180, by establishing a regulation to permit residues of microbial pesticide Dr. Biosedge (Puccinia canaliculata) in or on food crops. (PM-21)

14. *PP 2F4100.* ICI Americas, Inc., Agricultural Products, Concord Pike & New Murphy Rd., Wilmington, DE 19897, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of lambdacyhalothrin [1-alpha(S),3-alpha(Z)]-(±)-cyano-(3-phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate] in or on both dry bulb onions and garlic at 0.1 ppm. (PM-13)

15. *PP 2F4103.* FMC Corp., Agricultural Chemicals Group, 1735 Market St., Philadelphia, PA 19103, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of (±)-α-cyano-(3-phenoxyphenyl)l (±)*cis,trans*-3-(2,2-dichloro-ethenyl)-2,2-dimethylcyclopropane carboxylate (cypermethrin) and its metabolites dichlorovinyl acid (DCVA) and *m*-phenoxybenzoic acid (MPB Acid) in or on tomato fruit at 0.5 ppm. (PM-13)

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16. *PP 2F4104.* DowElanco, 9002 Purdue Rd., Indianapolis, IN 46268-1189, proposes to amend 40 CFR 180.417 by increasing the existing tolerance in milk from 0.01 ppm to 0.05 ppm, and establishing a tolerance for residues of triclopyr (3,5,6-trichloro-2-pyridinyloxyacetic acid) in or on apples at 0.05 ppm. (PM-25)

17. *PP 2F4105.* Ciba-Geigy Corp., Agricultural Division, P.O. Box 18300, Greensboro, NC 27419-8300, proposes to amend 40 CFR 180.408 by establishing a regulation to permit residues of the fungicide metalaxyl [N-(2,6-dimethylphenyl)-N-(methoxyacetyl)analine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)anilina methyl ester, each expressed as metalaxyl equivalents in or on nongrass animal feed forage at 6.0 ppm, non-grass animal feed hay at 20.0 ppm. (PM-21)

18. *PP 2F4106.* DowElanco, 9002 Purdue Rd., Indianapolis, IN 46268-1189, proposes to amend 40 CFR part 180 by establishing a regulation to permit combined residues of the soil microbiocide nitrapyrin [2-chloro-6-(trichloromethyl)pyridine and its metabolite, 6-trichloropicolinic acid in or on wheat forage at 2 ppm, wheat grain at 0.5 ppm, and wheat straw at 6 ppm. (PM-23)

19. *PP 2F4107.* Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419-8300, proposes to amend 40 CFR part 180 by establishing a regulation to permit residues of difenoconazole 1-[2-[4-chlorophenoxy]-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-yl-methyl)-1H-1,2,4-triazole in or on wheat forage at 0.1 ppm, wheat straw at 0.1 ppm, barley forage at 0.1 ppm, and barley straw at 0.1 ppm. (PM-21)

20. *PP 2F4109.* ICI Agricultural Products, Wilmington, DE 19897, proposes to amend 40 CFR 180.378 by establishing a regulation to permit residues of [1alpha(S),3alpha(Z)-(±cyano-(3-phenoxyphenyl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate in or on corn fodder at 3.0 ppm, corn grain field, pop and seed at 0.05 ppm, corn grain dust at 0.1 ppm, and corn silage at 1.0 ppm. (PM-13)

21. *PP 2F4110.* Nor-Am Chemical Co., 3509 Silverside Rd., P.O. Box 7495, Wilmington, DE 19803, proposes to amend 40 CFR 180.287 by establishing a regulation to permit the residues of the insecticide amitraz (N'-(2,4-dimethylphenyl]-N-[[(2,4-dimethylphenyl]imino] methyl]]-N-methylmethanimidamide) and its metabolites N-(2,4-dimethylphenyl)-N-methyl formamide and N-(2,4-dimethylphenyl)-N-methylmethanimide (both calculated as the parent) in or on liver at 0.4 ppm, fat at 0.2 ppm, and meat-by-products at 0.6 ppm of cattle, goats, hogs, horses, and sheep. (PM-19)

22. *PP 2F4114.* ICI Americas, Inc., Agricultural Products, Wilmington, DE 19897, proposes to amend 40 CFR 180.438 by establishing a regulation to permit residues of lambda-cyhalothrin [1 alpha(S), 3 alpha(Z)]-(+)-cyano(3-phenoxyphenyl)methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate in or on peanut hulls at 0.05 ppm and peanut nutmeats at 0.05 ppm. (PM-13)

23. *FAP 2H5618.* Nor-Am Chemical Co., P.O. Box 7495, 3509 Silverside Rd., Wilmington, DE 19803, proposes to amend 40 CFR part 185 by establishing a food additive regulation to permit residues of insecticide miticide amitraz (N'-(2,4-dimethylphenyl]-N-[[2,4-dimethylphenyl]imino]methyl]-N-methyl-methanimidamide) and its metabolites N-(2,4-dimethylphenyl)-N-methyl formamide and N-(2,4-dimethylphenyl)-N-methylmethanimidamide (both calculated as parent compound) in or on imported dried hops at 75 ppm. (PM-19)

24. *FAP 2H5619.* Sandoz Crop Protection Corp., 1300 East Touhy Ave., Des Plains, IL 60018, proposes to amend 40 CFR part 186 by establishing a feed additive for fluvalinate import tolerance in or on apple pomace, dry, at 2.0 ppm and hops, dried, at 15.0 ppm. (PM-13)

25. *FAP 2H5621.* BASF Corp., Agricultural Products Group, P.O. Box 13528, Research Triangle Park, NC 27709-3528, proposes to amend 40 CFR part 186 by establishing a feed additive regulation to permit residues of (ethoxyimino)butyl-5-(2-ethylthio)prop in or on canola-rape soapstock at 160.0 ppm and canola meal at 40.0 ppm. (PM-25)

26. *FAP 2H5625.* E.I. du Pont de Nemours & Co., Wilmington, DE 19880-0038, proposes to amend 40 CFR part 186 by establishing a feed additive petition for residues of the fungicide benomyl, methyl 1-butylcarbamoyl-2-benzimidazolecarbamate, in or on raisin waste at 50.0 ppm. (PM-21)

27. *FAP 2H5626.* EcoScience Corp., 85 North Whitney St., P.O. Box 300, Amherst, MA 01004, proposes to amend 40 CFR parts 185 and 186 by exempting from the requirement of a tolerance in or on processed food and animal feed *Metarhizium anisopliae* used for roach control. (PM-16)

28. *FAP 2H5627.* FMC Corp., Agricultural Chemical Group, 1735 Market St., Philadelphia, PA 10103, proposes to amend 40 CFR part 185 by establishing a food additive petition for cypermethrin (±)-a-cyano-(3-phenoxyphenyl)methyl (±)*cis,trans*-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate (cypermethrin) and its metabolites dichlorovinyl acid (DCVA) and *m*-phenoxybenzoic acid (MPB Acid) in or on sorghum flour at 1.5 ppm. (PM-13)

29. *FAP 2H5628.* Miles Inc., 8400 Hawthorn Rd., P.O. Box 4913, Kansas City, MO 64120-0013, proposes to amend 40 CFR part 185 by establishing a food additive petition for tebuconazole (*a*-[2-(4-chlorophenyl) ethyl]-*a*-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol) in or on peanut oil at 0.5 ppm and peanut soapstock at 0.5 ppm. (PM-21)

30. *FAP 2H5629.* Monsanto Co., Suite 1100, 700 14th St., NW., Washington, DC 20005, proposes to amend 40 CFR part 185 by establishing a feed additive petition to permit residues of the herbicide alachlor (2-chloro-2',6'-diethyl-N-(methoxymethyl) acetamide) and its metabolites (calculated as alachlor) in or on soybean grain dust at 2.0 ppm and soybean grain hulls at 1.0 ppm. (PM-25)

31. *FAP 2H5630.* BASF Corp., Agricultural Chemicals, P.O. Box 13528, Research Triangle Park, NC 27709-3528, proposes to amend 40 CFR part 186 by establishing a feed additive petition to permit combined residues of Poast herbicide, 2-[1-ethoxyimino)butyl]-5-[2-(ethylthio) propyl]-3-hydroxy-2-cyclohexen-1-one and its metabolites containing the 2-cyclohexen-1-one, in or on rice hulls at 0.2 ppm and rice bran at 0.2 ppm. (PM-25)

32. *FAP 2H5631.* FMC Corp., Agricultural Chemicals Group, 1735 Market St., Philadelphia, PA 19103, proposes to amend 40 CFR part 185 by establishing a food additive petition to permit the residues of cypermethrin (±)-a-cyano-(3-phenoxyphenyl)methyl(±)*cis,trans*-3-(2,2-dichloro-ethenyl)-2,2-dimethylcyclopropane carboxylate (cypermethrin) and its metabolites dichlorovinyl acid (DCVA) and *m*-phenoxybenzoic acid (MPB Acid) in or on tomato juice at 0.1 ppm, tomato puree at 0.1 ppm, tomato catsup at 0.2 ppm, tomato wet pomace at 1.0 ppm, and tomato dry pomace at 11.0 ppm. (PM-25)

33. *FAP 2H5633.* IR-4, Cook College, P.O. Box 231, Rutgers, State University of New Jersey, New Brunswick, NJ 08903-0231, proposes to amend 40 CFR part 185 by establishing a regulation to permit the residues of insecticide cyfluthrin (cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-

dimethylcyclopropanecarboxylate) in or on dried hops at 4.0 ppm. (PM-43)

34. *FAP 2H5634.* DowElanco, 9002 Purdue Rd., Indianapolis, IN 46268-1189, proposes to amend 40 CFR part 185 by establishing a food additive petition to permit combined residues of the soil microbiocide nitrapyrin [2-chloro-6-(trichloromethyl)pyridine] and its metabolite, 6-chloropicolinic acid, in or on wheat bran at 2 ppm and wheat shorts at 1 ppm. (PM-23)

35. *FAP 2H5635.* Monsanto Co., Suite 1100, 700 14th St., NW., Washington, DC 20005, proposes to amend 40 CFR 185.3500 by establishing a food additive petition to permit combined residues of glyphosate (N-phosphonomethyl)glycine) and its metabolites aminomethylphosphonic acid resulting from the application of the isopropylamine salt of glyphosate and/or the monoammonium salt of the glyphosate in or on wheat milling fractions (excluding flour) at 12 ppm. (PM-25)

36. *FAP 2H5636.* Miles, Inc., 8400 Hawthorn Rd., P.O. Box 4913, Kansas City, MO 64120-0013, proposes to amend 40 CFR part 186 by establishing a feed additive regulation to permit the residues of Bayleton, 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-2,4-triazol-1-yl)-2-butanone, in or on pineapple bran at 5.0 ppm. (PM-22)

37. *FAP 2H5638.* American Cyanamid Co., P.O. Box 0400, Princeton, NJ 08543-0400, proposes to amend 40 CFR part 186 by establishing a feed additive regulation to permit residues of the herbicide difenzoquat, (1,2-dimethyl-3,5-diphenyl-1H-pyrazolium ion), derived from application of the methyl sulfate salt and the cation, in or on barley milled fractions (except flour), and wheat milled fractions (except flour) at 1.0 ppm. (PM-23)

38. *FAP 2H5639.* Valent U.S.A. Corp., 1333 N. California Blvd., Suite 600, P.O. Box 8025, Walnut Creek, CA 94596-8025, proposes to amend 40 CFR part 185 by establishing a food additive regulation to permit residues of fenpropathrin, alpha-cyano-3-phenoxybenzyl 2,2,3,3-tetramethylcyclopropanecarboxylate, in or on cotton seed oil at 3 ppm, raisins at 15 ppm, orange oil at 160 ppm, cottonseed soapstock at 2 ppm, raisin waste at 45 ppm, and grape pomace, wet and dry at 35 ppm, orange pulp, dry at 8 ppm. (PM-13)

39. *FAP 2H5640.* Ciba-Geigy Corp., Agricultural Division, P.O. Box 18300, Greensboro, NC 27419-8300, proposes to amend 40 CFR parts 185 and 186 by establishing a food/feed additive petition to permit combined residues of cyromazine (N-cyclopropyl-1,3,5-triazine-2,4,6-triamine) and its principal metabolite melamine (1,3,5-triazine-2,4,6-triamine) calculated as cyromazine in or on processed tomato products at 1.2 ppm and dry tomato pomace at 1.6 ppm. (PM-18)

Amended Petitions

40. *FAP 2H5623.* BASF Corp., Agricultural Chemicals, P.O. Box 13528, Research Triangle Park, NC 27709-3528, proposes to amend 40 CFR part 185 by establishing a regulation to permit combined residues of vinclozolin, 3-(3,5-dichloro-phenyl)-5-ethenyl-5-methyl-2,4 oxazolidinedione, and its metabolites containing the 3,5-dichloroaniline moiety in or on potato dry peel at 3.0 ppm. Notice of this petition originally published in the **Federal Register** of March 11, 1992 (57 FR 8658), and proposed establishing tolerances for potato dry peel at 3.0 ppm and potato granules, flakes, and chips at 0.2 ppm. (PM-21)

41. *FAP 2H5624.* Nor-Am Chemical Co., 3509 Silverside Rd., P.O. Box 7495, Wilmington, DE 19803, proposes to amend 40 CFR part 185 by establishing a food additive tolerance for phenmedipham [3-methoxycarbonylaminophenyl-3'-methylcarbanilate] in or on sugar beet pulp, dehydrated at 0.5 ppm, and sugar beet molasses at 0.2 ppm. Notice of this petition originally published in the **Federal Register** of March 11, 1992 (57 FR 8659), and proposed amending 40 CFR 186.278 to establish a feed additive tolerance for phenmedipham in or on sugar beet pulp, dehydrated at 0.5 ppm, and sugar beet molasses at 0.2 ppm. (PM-25)

Corrected Petition

42. *PP 2F4039.* In the **Federal Register** of March 11, 1992 (57 FR 8658), EPA issued incorrectly an initial filing of PP 2F4039. It is corrected to read as follows: PP 2F4039. Scentry, Inc., 810 Central Ave., Billings, MT 59102, proposes to amend 40 CFR part 180 by establishing a regulation to exempt from the requirement of a tolerance the insect pheromone containing the active ingredients [E/Z]-4-tridecen-1-yl acetates in or on all raw agricultural commodities. (PM-18)

Authority: 7 U.S.C. 136a.

Dated: May 19, 1992.

Anne E. Lindsay,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 92-13821 Filed 6-9-92; 8:45 am]

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Page 39 is not included in this copy.

Pages ___ through ___ are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

✔ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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