Bharat Mathur,
Acting Regional Administrator, Region 5. [FR Doc. 04–10344 Filed 5–5–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0122; FRL–7356–8]

DCPA; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing 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 docket ID number OPP–2004–0122, must be received on or before June 7, 2004.

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: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you 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. 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. EPA Docket. EPA has established an official public docket for this action under docket ID number OPP–2004–0122. 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.

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. 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. Once in the system, select “search,” then key in the appropriate docket ID number.

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. 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 on 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
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.

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.


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–2004–0122. 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.

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

7. 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.

II. What Action is the Agency Taking?

EPA has received 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 Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.
List of Subjects
Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Bety Shackleford, Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition
The petitioner’s summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by Interregional Research Project Number 4 (IR-4), 681 and represents the view of the petitioner. 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.

Interregional Research Project Number 4 (IR-4)
PP 2E6442
EPA has received a pesticide petition 2E6442 from Interregional Research Project Number 4 (IR-4), 681 U.S. Highway 9, South, North Brunswick, NJ 08902–3390 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by section 408(d) of the FFDCA, 21 U.S.C. 08902–3390 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by

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Analytical method. Three tolerance enforcement methods for plant commodities are published in the Pesticide Analytical Manual (PAM), Vol. II (Section 180.185), as Methods A, B, and C. Residue data submitted in response to the 6/88 Guidance Document were collected using gas chromatography/electron capture (GC/EC) methods similar to the PAM, Vol. II methods. The Agency has found these methods to be adequate for collection of DCPA, HCB, MTP, and TPA residue data from potatoes (including processed commodities), sweet potatoes, barley, celery, cucumbers, green and bulb onions, strawberries, sweet and bell peppers, cantaloupes, tomatoes (including processed commodities), summer squash, and processed commodities of beans and cereals. The limits of detection (LOD) are 0.01 ppm for each of DCPA, MTP, and TPA, and 0.005 ppm for HCB. These methods are suitable candidates for validation procedures as enforcement methods for plant commodities.

Another GC/EC method, similar to those submitted for plants, is available for determining DCPA, MTP, and TPA in milk and beef fat. Recoveries of each compound using 12 samples each of milk and beef fat fortified at 0.01–5 ppm were acceptable. The LOD is 0.01 ppm. The Agency has deemed this method is suitable for its validation and inclusion in PAM, Vol. II pending successful independent laboratory validation. DCPA per se is completely recovered using PAM, Vol. I Multiresidue Protocols D and E (PESTDATA, PAM, Vol. I, Appendix, 8/93). Data submitted by the previous registrant indicate that TPA is not recovered by Protocols B and C. The Agency has indicated that multiresidue testing data on MTP are still required. The magnitude of residues—i. Oriental radish. IR-4 has received a request from California for the use of DCPA on oriental radish. IR-4 supports the requested tolerance of 2 ppm on oriental radish based on other existing tolerances.

ii. Basil. IR-4 has received a request from California for the use of DCPA on basil. IR-4 supports the requested tolerance of 5 ppm on basil based on other existing tolerances.

III. Coriander. IR-4 has received a request from California for the use of DCPA on coriander. IR-4 supports the requested tolerance of 5 ppm on coriander based on other existing tolerances.

iv. Dill. IR-4 has received a request from California for the use of DCPA on fresh dill. IR-4 supports the requested tolerance of 5 ppm on fresh dill based on other existing tolerances.

v. Marjoram. IR-4 has received a request from California for the use of DCPA on marjoram. IR-4 supports the requested tolerance of 5 ppm on marjoram based on other existing tolerances.

vi. Chives. IR-4 has received a request from California for the use of DCPA on chives. IR-4 supports the requested tolerance of 5 ppm on chives based on other existing tolerances.

B. Toxicological Profile
DCPA technical is classified under Toxicity Category IV (practically non-toxic) for acute oral toxicity and dermal irritation and Toxicity Category III (slightly toxic) for dermal lethal dose (LD₅₀), inhalation lethal concentration (LC₅₀), and eye irritation. DCPA is not a dermal sensitizer. DCPA has been classified as a Group C, possible human carcinogen, based on increased incidence of thyroid tumors in both sexes of the rat (although, only at an excessive dose in the female), and liver tumors in female rats and mice, at doses which were not excessive.

1. Acute toxicity. The acute oral LD₅₀ values for DCPA in the rat was 6,500 milligrams/kilogram (mg/kg). The acute dermal LD₅₀, was 2,000 mg/kg in the rabbit. The 4-hour rat inhalation LC₅₀ was 44.48 milligrams/per Liter (mg/L). DCPA was a mild irritant to rabbit skin and eyes. DCPA (performed with a 90% material) did not cause skin sensitization in guinea pigs.

2. Genotoxicity. Mutagenicity studies shown below have demonstrated that
DCPA is non-mutagenic both in vivo and in vitro. DCPA did not induce a mutagenic response in two independently performed mouse lymphoma forward mutation assays. The nonactivated concentration range was 7.5 to 100 milligrams/milliliter (mg/mL) and the S9-activated range was 15 to 200 mg/mL (MRID 41054822). In an in vitro cytogenetic assay, Chinese hamster ovary cells were exposed to DCPA at dose levels of 0, 30, 100, 300, or 1,000 mg/mL for 4 hours both with and without S9 activation. Cells were harvested at 12 and 18 hours. There were no indications of a clastogenic response as a result of exposure to test material at any dose level (MRID 41054823). DCPA was not genotoxic in two independently performed unscheduled DNA synthesis (UDS) assays in which the concentration ranged from 3 to 1,000 mg/mL (MRID 41054824). An in vitro assay for sister chromatid exchange (SCE) in Chinese hamster ovary cells was performed at dose levels of 0, 38, 75, 150, or 300 mg/mL both with and without S9 activation. There was no indication of a positive response; therefore, under the conditions of this assay the test material is negative (MRID 41054825).

3. Reproductive and developmental toxicity. A developmental toxicity study with Sprague Dawley rats used doses of 0, 500, 1,000, or 2,000 mg/kg/day given by gavage on gestation days 6–15. There were no adverse effects on the maternal rats or their offspring that were observed. Therefore, the maternal NOEL was set at 2,000 mg/kg/day, highest dose tested (MRID 41060685).

Two studies were conducted with New Zealand white rabbits. In the first study, DCPA doses of 0, 500, 1,000, or 1,500 mg/kg/day were given by gavage on gestation days 6–19. There were maternal deaths and adverse clinical signs at all dose levels. In the second study, DCPA doses of 0, 125, 250, or 500 mg/kg/day were given by gavage on gestation days 7–19. None of these levels produced any maternal or developmental toxicity. The second study tested dose levels that overlapped those in the first study. Therefore, when considered together, the no observed adverse effect level (NOEL) for maternal toxicity can be set at 250 mg/kg and the lowest observed adverse effect level (LOAEL) can be set at 500 mg/kg based on maternal deaths. The developmental toxicity NOEL can be set at 500 mg/kg. Although, no developmental toxicity was observed at any of the higher dose levels, a higher NOEL cannot be set based on the limited number of litters at the higher dose levels.

In a 2-generation reproduction study, female Sprague Dawley rats were fed DCPA at doses of 0, 63, 319, or 1,273 mg/kg/day while males received doses of 45, 233, or 952 mg/kg/day DCPA. These doses were equivalent to 0, 1,000, 5,000, and 20,000 ppm food residue values, which the Agency used in mammalian environmental risk. No effects on reproductive performance in 2 generations with 2 litters per generation were seen. The maternal NOEL was 63 mg/kg/day. The maternal LOAEL was 319 mg/kg/day, based on decreased body weight/body weight gain. The reproductive NOEL was 63 mg/kg/day. The LOAEL was 319 mg/kg/day, based on decreased pup body weight. The paternal NOEL was set at 233 mg/kg/day, and the LOAEL was set at 952 mg/kg/day due to decreased body weight gain. On day 0 of the F2b litters, the diets for the low and mid-dose groups were changed to 10 and 20 mg/kg/day respectively to be able to set NOEL for pup body weight. The offspring NOEL was set at 18 mg/kg/day (200 ppm), and the LOAEL was 47 mg/kg/day (500 ppm) based on decreased body weight (MRIDs 41750103, 41905201).

4. Subchronic toxicity. In a 21-day dermal toxicity study, Charles River CD rats were dermally exposed to DCPA at doses of 0, 10, 50, 150, or 1,000 mg/kg/day. There were no dermal irritation at the site of application was observed. No adverse effects were found; therefore, the NOEL was either equal or greater than 1,000 mg/kg/day, the highest dose tested (MRID 41231803). CD VAF Plus Sprague Dawley rats were given 0, 10, 50, 100, 150, or 1,000 mg/kg/day of DCPA in the diet for 90 days. The NOAEL was 10 mg/kg/day. The LOAEL was 50 mg/kg/day, based on increased liver weight and microscopic effects. The treatment-related effects were: Increased liver weight and centrilobular hypertrophy in the liver; increased accumulation of foamy macrophages in the lung; increased weight, epithelial hyperplasia, and tubular hypertrophy of the kidney; and follicular hypertrophy of the thyroid. There were slight decreases in body weight and food consumption in high dose males only (MRID 41767901).

In another combined chronic toxicity and carcinogenicity study, CD-1 mice were given DCPA in the diet for 2 years. The doses were 0, 12, 123, 435, or 930 mg/kg/day DCPA in the diet for males and 0, 15, 510, 1,141 mg/kg/day for females. The NOAEL for systemic effects was 435 mg/kg/day in males; 510 mg/kg/day in females. The systemic lowest observed effect level (LOEEL) was 930 mg/kg/day for males and 1,141 mg/kg/day in females, based on liver effects. There were increased liver weights,
increased SDH (sorbital dehydrogenase) and GPT (glutamic-pyruvic transaminase) activities, and increased incidence of hepatocyte enlargement or vacuolation in both sexes at the high dose levels; 930 and 1,141 mg/kg/day for males and females, respectively. There was a significant increase in hepatocellular neoplasms in females at the high dose level of 1,141 mg/kg/day. Corneal opacity was observed in this study (MRID 40958701).

Additionally, a supplementary rat chronic ophthalmology study was conducted to investigate the corneal opacity observed in the mouse study. There was no evidence of ocular toxicity observed in rats fed DCPA in the diet at levels up to 1,000 mg/kg/day for 2 years (MRID 41750102).

6. Animal metabolism. In one study, a single oral dose of 14\textsuperscript{C}-DCPA at either 1 or 1,000 mg/kg was given to Sprague-Dawley rats (5 rats/sex/dose level). The major metabolite of DCPA in the urine of both sexes at both dose levels was 4-carboxymethoxy-2,3,5,6-tetrachlorobenzene. No radiolabel was excreted in the urine as the parent compound, DCPA (MRID 42155501).

There was a second study in which a single oral dose of 14\textsuperscript{C}-DCPA at either 1 or 1,000 mg/kg was given to Sprague-Dawley rats. Bile was found to be a negligible excretory route for radiolabeled DCPA. At the low dose, 61% of the administered radiolabeled DCPA was excreted in the urine. The percent absorption (urine, blood, bile, cage rinse, and carcass) was 79% of the administered dose. At the high dose, 55% of the administered radiolabel was excreted in the feces or was found in the GIT (gastro-intestinal tract). The percent absorption was 8% of the administered dose (MRID 412155503).

There was a third study in which a single oral dose of 14\textsuperscript{C}-DCPA at either 1 or 1,000 mg/kg was given to Sprague-Dawley rats (3 rats/sex/dose level) to determine the major route of excretion. Urine was the major route at the low dose, and feces was the major route at the high dose. Negligible amounts of radiolabel were found in the tissues examined at 48 hours following dosing. There were no significant differences observed between the sexes at either dose level (MRID 42155502).

In a different study, nonradiolabeled DCPA was administered in single, daily oral doses to C57:CD BR VAF/Plus rats (15 rats/sex/dose level) for 14 consecutive days at either the 1 or 1,000 mg/kg/day dose level. Twenty-four hours after the single dose, a single oral dose of 14\textsuperscript{C}-DCPA (1 or 1,000 mg/kg) was administered to each rat. At the high dose level (both sexes), the majority of the administered 14\textsuperscript{C}-DCPA was unabsorbed and was eliminated in the feces, while at the low dose level (both sexes) the majority of the administered 14\textsuperscript{C}-DCPA was absorbed and excreted in the urine. Radiolabel was found in all tissues examined, and the radiolabel concentration was higher in the high-dose rat tissue than in the same tissue at the low dose level. At 168 hours, radiolabel was still detectable in nearly all tissues at both dose levels and in both sexes. The elimination half-life of radiolabel was calculated to be 22–23 hours at the high dose and approximately 18–hours at the low dose. (MRID 42723201, 42723202).

In another study, Sprague-Dawley rats (5 rats/sex/dose level) were given single or multiple 14–days oral doses of 14\textsuperscript{C}-DCPA (1 or 1,000 mg/kg). The major metabolite of DCPA in the urine of both sexes at both dose levels following both single and multiple dosing was 4-carboxymethoxy-2,3,5,6-tetrachlorobenzene acid. A minor metabolite was tetrachloroethene acid. Negligible amounts of radiolabel were excreted in the urine as the parent compound, DCPA (MRID 42723203). Together these studies fulfill GLN 870.7485 (old GLN 85–1) (MRID 43052201).

7. Metabolite toxicology—i. Hexachlorobenezene (HCB) as a DCPA impurity. HCB is a recognized impurity in DCPA. The Agency has classified HCB as a B2 (probable human) carcinogen, based on data sets which showed significant increases of tumor incidence in 2 species: Hamsters and rats. In a 130-week feeding study in rats, the NOAEL was 0.08 mg/kg/day. (Effects observed were hepatic centrilobular basophilic chromogenesis.) The dermal absorption factor of HCB is 26.46% (MRID 42651501). At this time no other toxicological endpoints of concern have been identified for HCB.

The Agency risk assessment of HCB was based on levels in the original DCPA source material. Since then, the Agency has acknowledged in RED correspondence that the new registrant committed to reducing HCB concentrations in its source material. Subsequently, the Agency in fact confirmed a new technical registration (granted to AMVAC Chemical Corporation) with HCB concentrations almost two orders lower in magnitude than before. As a result, the potential HCB exposures to humans is concomitantly reduced to a fraction of the potential exposure considered by EPA in its original RED risk assessment.

ii. Polyhalogenated dibenzo-p-dioxins/dibenzofurans (dioxin/furans) are recognized impurities of DCPA. Of the dioxin/furans, only the 2,3,7,8-tetrachlorodibeno-paradioxins (2,3,7,8-TCDD) congener has been assigned a quantified estimate of its carcinogenic potential. The Agency has classified 2,3,7,8-TCDD as a B2 (probable human) carcinogen based on data sets which showed significant increases of tumor incidence in 2 species: Sprague-Dawley rats and B6C3F1 mice.

Enough data exist, however, regarding the potency of the other congeners to estimate their relative potency in comparison to the 2,3,7,8-TCDD. Therefore, in evaluating the toxicological significance of the dioxin/furan contamination, the Agency converts all of the congener detection values into one value which represents the equivalent 2,3,7,8-TCDD potency. For example, if a product contained 10 parts per billion (ppb) of a dioxin congener other than the 2,3,7,8-TCDD, the Agency would use the equivalent of 1 ppb of 2,3,7,8-TCDD in its risk assessment. DCPA’s prior registrant submitted dioxin/furan detection values to the Agency from seven batch samples, as required in the 1987 DCPA.

During the first sampling, one of the dioxin/furan congeners was detected above the Agency specified level of quantitation (LOQ). The manufacturing process was subsequently altered in an effort to reduce this contamination. (MRID 41241801). Subsequent to this change, none of the other dioxin/furan congeners were detected above Agency specified LOQs in the remaining six batch samples. The 2,3,7,8-TCDD equivalency of the dioxin/furans reported to the Agency is approximately 0.1 ppb, which would equal 0.00000001% of the DCPA formulations. The Agency used this contamination value (0.00000001%) to determine exposure values used in the risk assessments for DCPA’s reregistrant eligibility evaluation. The Agency required registrants to propose certified upper limits for all dioxin/furan congeners for which detection values were reported to the Agency.

The reference dose (RFD) for 2,3,7,8-TCDD is 0.000001 µg/kg/day based on a LOAEL of 0.001 µg/kg/day from a three-generation feeding study in rats. (Effects at the lowest dose tested included dilated renal pelvises, decreased fetal weight, and changes in the gestational index). An uncertainty factor of 100 was used to account for the interspecies extrapolation factor and intraspecies variability. An additional uncertainty factor of 10 was used to...
account for the lack of a NOAEL. At this
time, no other toxicological endpoints of
concern have been identified for 2,3,7,8-
TCDD.

iii. Tetrachloroterephthalic acid (TPA)
as a DCPA metabolite.
tetracloro-tereaphthalic acid (TPA) is
one of two DCPA animal metabolites.
DCPA fed to lactating goats was
metabolized into both TPA and
monomethyl tetrachloroterephthalic
acid (MTP). It is the TPA metabolite,
however, that is found most frequently
in the environment after DCPA use. Soil
metabolism converts DCPA into TPA,
which is known to leach through soil
and pollute ground water. Therefore, the
prior registrant submitted the following
additional studies to specifically assess
the toxicity of TPA.

8. Subchronic toxicity of TPA.
Disodium 2,3,5,6-
tetrachloroterephthalic acid was given
to Charles River CD rats in the diet for
13-weeks. There were 15 rats/sex/dose
group using dose levels of 0, 2.5, 50,
or 500 mg/kg/day. There were no
adverse effects in either sex at any dose
level. The NOAEL is greater than or
equal to 500 mg/kg/day, the highest
dose tested. The LOAEL cannot be
determined (MRID 00100773).

CD Sprague-Dawley rats (10/sex/dose
group) were given 2,3,5,6-
tetrachloroterephthalic acid via gavage for
30 days at dose levels of 0, 100, 500,
or 2,000 mg/kg/day. There were no
apparent adverse effects observed at any
dose level. The NOAEL is greater than or
equal to 2,000 mg/kg/day, the highest
dose tested. The LOAEL cannot be
determined. (MRID 00158011).

9. Developmental toxicity of TPA. In a
developmental toxicity study, 25
pregnant Charles River rats/dose group
were dosed via gavage on gestation days
6-15 with TPA at dose levels of 0, 625,
1,250, or 2,500 mg/kg/day. The maternal
factor NOEL was 1,250 mg/kg/day.
The maternal LOAEL was set at 2,500
mg/kg/day based on decreased body-
weight gain and food consumption.
There were no signs of developmental
toxicity, therefore, the developmental
NOAEL was set at 2,500 mg/kg/day, the
highest dose tested. A LOAEL was not
determined (MRID 262303).

10. Mutagenicity of TPA. TPA did not
induce a mutagenic response in the
Ames assay or the HGPRT assay with or
without metabolic activation (MRID
262302). In the Sister Chromatid
Exchange (SCE) assay, TPA did not
induce a significant increase in the SCE
frequency of Chinese hamster ovary
cells, both with and without metabolic
activation. TPA did not induce an
increase in unscheduled DNA synthesis.
In an in vivo mouse micronucleus assay,
TPA was negative for clastogenicity in
females and at best equivocal in males.
Based on the overall weight of evidence
of no mutagenic response of this
compound in other studies, as well as the
lack of mutagenicity of the parent
DCPA, further testing for mutagenicity is
not warranted at this time.

11. Endocrine disruption. The
toxicity data base for DCPA is current
and complete. Studies in this data base
include evaluation of the potential
effects on reproduction and
development, and an evaluation of the
pathology of the endocrine organs
following short-term or long-term
exposure. These studies revealed no
primary endocrine effects due to DCPA.

C. Aggregate Exposure

1. Dietary exposure—i. Food.
Tolerances for residues of DCPA in or
on raw agricultural commodities are
currently expressed as the combined
residues of DCPA and its metabolites
monomethyl tetrachloroterephthalate
(MTP) and tetrachloroterephthalic acid
(TPA) calculated as DCPA. At present,
tolerances exist for residues of DCPA in
animal commodities. Although, all
the data requirements of the
Reregistration Guidance had not been
met when the Agency issued the RED,
the outstanding data were considered to
be confirmatory to the reregistration
eligibility decision. The Agency
determined that sufficient data are
available to conduct reasonable
anticipated residue assessments.

People may be exposed to residues of
DCPA through the diet. Tolerances or
maximum residue limits have been
established for residues of DCPA in
many food and feed crops (see 40 CFR
180.185). EPA has reassessed the DCPA
tolerances and found that some are
acceptable, others must be revoked
because refinements in crop groups
must be replaced with new tolerances
for the new crop groupings. Acute
dietary risk assessments were not
necessary since there were no acute
toxicological endpoints of concern for
DCPA or its impurities. Chronic and
carcinogenic dietary risks were
assessed, however, due to exposure to
DCPA, HCB, and dioxin/furans.

Chronic risk estimates for the U.S.
population and all subgroups were well
below 100% of the RfD for DCPA, HCB,
and dioxin/furans. Based on these
estimates, the Agency concluded that
DCPA use does not pose a significant
chronic dietary risk. Carcinogenic risk
estimate for exposure to DCPA, HCB,
and dioxin/furans through food were
2.8 x 10-5, 5 x 10-7, and 7 x 10-5,
respectively. All of these risk estimates
are within the range (zero to 1 x 10-6)
generally considered to
be negligible by the Agency. Thus, the
Agency concluded that DCPA use does
not pose a significant excess lifetime
cancer risk.

ii. Drinking water. The Agency
assessed both chronic (non-cancer) and
carcinogenic risk due to exposure to
DCPA and its metabolites through
contaminated ground water and surface
water. The Agency used annual
contamination averages from five
geographic regions as potential drinking
water exposure values. The highest
annual average was 50 ppb in New York
from a turf study. Although, this
represents approximately 71% of the
health advisories (HA), it only
corresponds to 11% of RfD. Even if part
of this population were to the maximum
3% of the RfD from other dietary
sources, the chronic dietary risk would
still be considered minimal.

Individual excess lifetime cancer risk
from the New York turf site was 1.7 x
10-4. The next highest risk estimate is
based on data from Suffolk County, New
York. The risk estimate from that site
is 9.7 x 10-4. DCPA’s previous registrant
voluntarily withdrew from selling the
product in Suffolk, New York. Exposure
values from all other sites resulted in
risks below the Agency’s cancer
benchmark of 1 x 10-4. Based on these
estimates, the Agency concluded that
DCPA and its metabolites do not
currently pose a significant cancer or
chronic non-cancer risk from non-turf
uses to the overall U.S. population from
exposure through contaminated
drinking water.

2. Non-dietary exposure. DCPA is
currently registered for commercial and
residential use. Risk assessments were
performed to assess the individual
excess lifetime cancer risk from DCPA
and HCB resulting from occupational
and residential exposure to DCPA. The
Agency will not generally allow non-
dietary risks to exceed 10-6, except in
cases where EPA has determined that
benefits exceed the risks.

i. Occupational exposure. Risk was
estimated for occupational exposures to
both DCPA and HCB. The highest risk
for both commercial applicators and
private applicators is associated with
the use of the wettable powder
formulation. For the commercial
applicator, the highest risk for DCPA
was estimated to be 7.5 x 10-5 and for
HCB (in DCPA) to be 1.9 x 10-5. The
Agency is requiring mixer/loader/
applicators using DCPA wettable
powders to wear a dust-mist respirator
fitted with a TC-21 filter to mitigate this
risk. Wearing a dust-mist respirator
reduces the risks to 4.0 x 10-5 and 1.3
x 10-5 for DCPA and HCB respectively.
For the private applicator, the highest risk for DCPA was estimated to be 1.6 x 10^{-4} and for HCB (in DCPA) to be 4.6 x 10^{-6}.

ii. Turfgrass. Risks to children playing on a treated lawn were assessed for exposure to DCPA and HCB. The risks from DCPA and HCB to children playing on an irrigated lawn are 5.6 x 10^{-7} and 3.9 x 10^{-7}, respectively. The risks from DCPA and HCB to children playing on non-irrigated lawns are 2.0 x 10^{-6} and 2.7 x 10^{-6}, respectively. The Agency is conducting a risk/benefit assessment to determine whether the turf use is eligible for reregistration. However, in the interim, the Agency is requiring that residential lawns be watered after DCPA product use and that reentry not occur until sprays have dried, in an effort to mitigate risks to children.

iii. Re-entry. Risk from exposure to DCPA and HCB through worker re-entry into a cucumber field was assessed. Harvesting cucumbers immediately after application resulted in risk estimates of 1.8 x 10^{-6} for DCPA and 3.2 x 10^{-6} for HCB. Delayed re-entry periods only minimally reduced risk estimates.

However, the Agency reported in the RED that it believes that the worker exposures are overestimates. These scenarios were based solely on a foliar dissipation study, not on dermal exposure studies. DCPA’s current registrant is a member of a task force which will address dermal exposure for hand labor tasks required by various crops, such as cucumber harvesting. The risk assessment will be refined when the task force submits its dermal exposure data.

D. Cumulative Effects

DCPA is a pre-emergent herbicide used to control annual grasses and broadleaf weeds. At this time, the EPA has not made a determination that DCPA and other substances that may have a common mechanism of toxicity would have cumulative effects. Therefore, for these tolerance petitions, it is assumed that DCPA does not have a common mechanism of toxicity with other substances and only the potential risks of DCPA in its aggregate exposure are considered.

E. Safety Determination

DCPA and its metabolites generally are of low acute and chronic toxicity. DCPA has been classified as a Group C, possible human carcinogen. Many food crop uses are registered, however, dietary exposure to DCPA residues in foods is at a low level, as is the cancer risk posed to the general population.

Of greater concern is the risk posed to DCPA handlers, particularly mixers/loaders/applicators, and field workers who come into contact with treated areas following application of this pesticide. Exposure and risk to workers will be mitigated by the use of personal protective equipment required by the Worker Protection Standard. Because the pesticide is a possible human carcinogen, the Agency required mixer/loader/applicators using DCPA wettable powder to wear a dust-mist respirator fitted with a TC-21 filter to mitigate this risk.

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient specific) data required to support reregistration of products containing DCPA. The Agency completed its review of these generic data, and determined that the data are sufficient to support reregistration of all products containing DCPA under the conditions specified in the RED. The generic data that the Agency reviewed as part of its determination of reregistration eligibility were sufficient to allow the Agency to assess the registered uses of DCPA and to determine that DCPA can be used without resulting in unreasonable adverse effects to humans and the environment, if used according to the labels as amended by the RED. The Agency, therefore, found that all products containing DCPA as the active ingredient are eligible for reregistration under the conditions specified in the RED.

F. International Tolerances

No maximum residue limits for DCPA have been established by Codex for any agricultural commodity. Therefore, no compatibility questions exist with respect to U.S. tolerances.

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FEDERAL COMMUNICATIONS COMMISSION

Federal Advisory Committee Act Notice of Public Meeting

AGENCY: Federal Communications Commission.

ACTION: Notice of public meeting extension.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, this notice advises interested persons that the Advisory Committee on Diversity for Communications in the Digital Age will hold its third meeting on June 14, 2004. The Federal Communications Commission has decided to postpone the original date of its third meeting, which was scheduled for May 10, 2004. The meeting will now be held at the Federal Communications Commission in Washington, DC on Monday, June 14, 2004. The Diversity Committee was established by the Federal Communications Commission to examine current opportunities and develop recommendations for policies and practices that will further enhance the ability of minorities and women to participate in telecommunications and related industries.

DATES: June 14, 2004, 2 p.m. to 5 p.m.


FOR FURTHER INFORMATION CONTACT: Jane E. Mago, Designated Federal Officer of the Committee on Diversity, or Maureen C. McLaughlin, Alternate Designated Federal Officer of the Committee on Diversity, (202) 418–2030, e-mail jane.mago@fcc.gov, Maureen.Mclaughlin@fcc.gov, Press Contact, Audrey Spivak, Office of Public Affairs, (202) 418–0512, aspivak@fcc.gov.

SUPPLEMENTARY INFORMATION: The Diversity Committee was established by the Federal Communications Commission to examine current opportunities and develop recommendations for policies and practices that will further enhance the ability of minorities and women to participate in telecommunications and related industries. The Diversity Committee will prepare periodic and final reports to aid the FCC in its oversight responsibilities and its regulatory reviews in this area. In conjunction with such reports and analyses, the Diversity Committee will make recommendations to the FCC concerning the need for any guidelines, incentives, regulations or other policy approaches to promote diversity of participation in the communications sector. The Diversity Committee will also develop a description of best practices within the communications sector for promoting diversity of participation.

During the June 14, 2004, meeting will include reports from the Diversity Committee’s four subcommittees, discussing progress towards the final