Dated: April 19, 2004.

Bharat Mathur,

Acting Regional Administrator, Region 5.

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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

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

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2004–0122. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID number OPP–2004–0122. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

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

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID number OPP–2004–0122.

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.

Dated: April 26, 2004.

Betty 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 #1 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 establishing a tolerance for residues of DCPA, or chlorthal dimethyl (dimethyl tetrachloroterephthalate) in or on the raw agricultural commodities Oriental radish, basil, coriander, dill, marjoram, chives, ginseng, celeriac, chicory, mradicchio, parsley (fresh) and parsley (dried) at 2.0, 5.0, 5.0, 5.0, 5.0, 5.0, 2.0, 2.0, 5.0, 2.0, 5.0 and 15 parts per million (ppm), respectively. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; 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.

A. Residue Chemistry

1. *Plant metabolism*. The qualitative nature of the residue in plants is adequately understood based on acceptable studies on onions, turnips, and tobacco. The residues of concern in plants are DCPA, and its metabolites monomethyl tetrachloroterephthalic acid (MTP) and tetrachloroterephthalic acid (TPA) which are the parent and metabolites that are currently regulated. The proposed metabolism of DCPA in plants is via ester hydrolysis. Studies conducted with onion and turnip indicate that the impurity hexachlorobenzene (HCB) is not metabolized appreciably in these plants.

2. *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, broccoli, celery, cucumbers, green and bulb onions, strawberries, sweet and bell peppers, cantaloupes, tomatoes (including processed commodities), summer squash, and processed commodities of beans and cottonseed. The limits of detection (LOD) are 0.01 ppm each for DCPA, MTP, and TPA, and 0.0005 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.

3. *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.

vii. *Ginseng*. IR-4 has received requests from Wisconsin and North Carolina for the use of DCPA on ginseng. IR-4 supports the requested tolerance of 2 ppm on ginseng based on other existing tolerances.

viii. *Celeriac*. IR-4 has received a request from California for the use of DCPA on celeriac. IR-4 supports the requested tolerance of 2 ppm on celeriac based on other existing tolerances. Chicory: IR-4 has received a request from California for the use of DCPA on chicory. IR-4 supports the requested tolerance of 5 ppm on chicory based on other existing tolerances.

ix. *Radicchio*. IR-4 has received a request from California for the use of DCPA on radicchio. IR-4 supports the requested tolerance of 2 ppm on radicchio 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 $(LD)_{50}$, inhalation lethal concentration $(LC)_{50}$, 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 LD_{50} values for DCPA in the rat was >5,000 milligrams/kilogram (mg/kg). The acute dermal LD_{50} was >2,000 mg/kg in the rabbit. The 4–hour rat inhalation LC_{50} was >4.48 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 as 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 S-9 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. No adverse effects on the maternal rats or their offspring were observed. Therefore, the maternal and developmental toxicity no observed effect levels (NOELs) were set at 2,000 mg/kg/day, highest dose tested (MRID 00160685).

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 (NOAEL) 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 NOAEL can be set at 500 mg/kg. Although, no developmental effects were observed at any of the higher dose levels, a higher NOAEL 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 NOAEL was 63 mg/kg/day. The maternal LOAEL was 319 mg/kg/day, based on decreased body weight/body weight gain. The reproductive NOAEL was 63 mg/kg/day. The LOAEL was 319 mg/kg/day, based on decreased pup body weight. The paternal NOAEL 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 18 and 47 mg/kg/day respectively to be able to set a NOAEL for pup body weight. The offspring NOAEL 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 doses of 0, 100, 300, or 1,000 mg/kg/day. No dermal irritation at the site of application was observed. No adverse effects were found; therefore, the NOEL was equal to 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 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 females only (MRID 41767901).

Male CD-1 mice were given doses of 0, 100, 199, 406, or 1,235 mg/kg/day DCPA and females were given 0, 223, 517, 1049, or 2,198 mg/kg/day DCPA in the diet for 90 days. There were no effects other than minimal histopathological effects on the liver. The NOAEL was 406 mg/kg/day for males and 517 mg/kg/day for females. The LOAEL for males was 1235 mg/kg/day and for females was 1,049 mg/kg/day, based on the liver effects (MRID 41064801).

5. *Chronic toxicity.* Beagle dogs were given 0, 2.5, 25, or 250 mg/kg/day DCPA in the feed for 2 years. Adverse effects were not found. Therefore, the NOAEL was equal to or greater than 250 mg/kg/day (MRID 00083584).

A chronic toxicity and carcinogenicity study was conducted with Sprague Dawley CD rats. The doses of DCPA given in the diet for 2 years were 0, 1, 10, 50, 500 or 1,000 mg/kg/day. The NOAEL was 1 mg/kg/day. The LOAEL was 10 mg/kg/day, with effects observed in the lungs, liver, and thyroid; decreases in thyroid hormone levels in both sexes; and effects in eyes in females. The specific effects were: (1) Increased mortality in males at 1,000 mg/kg/day HDT during the second year; (2) either decreased body weights or decreased body weight gains in both sexes at 1,000 mg/kg/day, and in females at 500 mg/kg/day; (3) changes in hematology and clinical chemistry parameters indicative of liver and kidney toxicity at both 500 and 1,000 mg/kg/day in both sexes; (4) treatment-related increases in thyroid, liver, and kidney weights in both sexes; (5) a dose-related increase in white foci in the lungs, which correlated with an increased incidence of foaming macrophages in both sexes at doses of 10 mg/kg/day and higher; (6) treatment-related exacerbation of chronic nephropathy in both sexes at 50 mg/kg/day and higher; (7) a dose-related increase in centrilobular hepatocytic swelling in both sexes at doses of 10 mg/kg/day and higher; (8) a dose-related increase in liver neoplasms in females; (9) an increase in follicular cell hyperplasia/hypertrophy at 10 mg/kg/day in males and at doses of 50 mg/kg/day and higher in both sexes; (10) decreased T4 (thyroid hormone/thyroxine) values at 10 mg/kg/day in males, and at 50 mg/kg/day and higher in both sexes; and (11) a treatment-related increase in thyroid follicular cell neoplasms in both sexes (MRID 42731001).

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, 150, 510, or 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 (LOEL) was 930 mg/kg/day in males; 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^{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-carbomethoxy-2,3,5,6-tetrachlorobenzoic acid. 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^{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 42155503).

There was a third study in which a single oral dose of 14^{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 Crl: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 14^{th} dose, a single oral dose of 14^{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^{C}-DCPA was unabsorbed and was eliminated in the feces, while at the low dose level (both sexes) the majority of the administered 14^{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^{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-carbomethoxy-2,3,5,6-tetrachlorobenzoic acid. A minor metabolite was tetrachloroterephthalic acid. No radiolabel was 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. Hexachlorobeneze (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 as DCPA Impurities.* Polyhalogenated dibenzo-p-dioxins/dibenzofurans (dioxin/furans) are recognized impurities of DCPA. Of the dioxin/furans, only the 2,3,7,8-tetrachloro-dibenzo-para-dioxin (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, and if that congener is considered to be only $1/10^{th}$ as potent as 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 DCI. 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 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 reregistration 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 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.* tetrachloro-terephthalic 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, 25, 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 toxicity 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 toxicology 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, no 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 3.5 x 10^{-7}, and 7 x 10^{-8}, 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^{-6}. 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^{-7}. 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^{-6}. 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^{-4}, 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^{-4}. 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^{-4} for DCPA and HCB respectively.

For the private applicator, the highest risk for DCPA was estimated to be 1.6 x 10^{-6} 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^{-4} for DCPA and 3.2 x 10^{-4} 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 it 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 of 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.

ADDRESSES: Federal Communications Commission, Commission Meeting Room, Room TW–C305, 445 12th St., SW., Washington, DC 20554.

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.

Agenda

The June 14, 2004, meeting will include reports from the Diversity Committee's four subcommittees regarding progress towards the final