request letters and the MOA, shipping such stocks for export consistent with the requirements of section 17 of FIFRA, or proper disposal.

5. *Retail and other sale or distribution of indoor end-use products.* Sale or distribution by any person of the existing stocks of any product identified in Table 3 or Table 4 that bear instructions for indoor use will not be lawful under FIFRA after December 31, 2002, except for the purposes of returns for re-labeling consistent with the Technical Registrants' cancellation request letters and the MOA, shipping such stocks for export consistent with the requirements of section 17 of FIFRA, or proper disposal.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: April 24, 2001.

Lois Rossi,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 01–10998 Filed 5–1–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1017; FRL–6779–1]

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 control number PF–1017, must be received on or before June 1. 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1017 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9368; e-mail address: jamerson.hoyt@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' ''Regulation and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–1017. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1017 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–1017. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this

document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified 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 control 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 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 18, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Interregional Research Project Number 4 (IR-4)

PP 5E4557

EPA has received a pesticide petition (5E4557) from Interregional Research Project #4 (IR-4), Center for Minor Crop Pest Management, Rutgers, The State University of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of the fungicide dicloran, 2,6-dichloro-4-nitroaniline, in or on the raw agricultural commodity leafy greens subgroup (except spinach) at 10 parts per million (ppm). 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 metabolism of dicloran in peaches, lettuce and potatoes has been studied. Parent compound and numerous metabolites derived by hydroxylation and acetylation of the nitro group, along with deamination and hydroxylation of the amino group, were seen in all crops. Glutathione conjugation with simultaneous removal of one or both chlorine atoms was shown to occur.

2. *Analytical method*. An adequate analytical method electron capture/gas liquid chromatography (EC GLC) is available for enforcement purposes. Parent compound is the only analyte in the tolerance expression.

3. *Magnitude of residues*. Existing tolerances for dicloran in lettuce and endive, which are also in Crop Subgroup 4-A, are supported by residue studies which have been previously reviewed by EPA. Tolerances for two other crops in Crop Group 4, celery and rhubarb, also exist. The existing data support the conclusion that residues of dicloran will not exceed 10 ppm for the leafy greens subgroup (except spinach).

B. Toxicological Profile

1. *Acute toxicity*. The acute oral lethal dose 50 (LD_{50}) of technical dicloran is greater than 10,000 milligrams/kilogram (mg/kg), the acute dermal LD_{50} is greater than 2,000 mg/kg, and the 4–hour acute inhalation lethal concentration 50 (LC_{50}) is greater than 2 mg/liter. Dicloran is not a dermal irritant but is a sensitizer. Dicloran is a mild eye irritant.

2. *Genotoxicity*. The following genotoxicity tests were conducted: gene mutation (Ames tests), structural chromosome aberration (*in vivo* cytogenetic assay using human lymphocytes) and unscheduled DNA synthesis using rat hepatocytes. Results were generally negative; however, some Ames tests with the bacterium *S. typhimurium* showed a positive response. Ames tests with *E. coli* were negative. In view of the results of mammalian chronic, carcinogenic and developmental studies, however, Gowan Company considered that the results of the positive Ames tests are not relevant to human toxicity.

3. *Reproductive and developmental toxicity*. In a rabbit developmental toxicity study, the maternal no observed adverse effect level (NOAEL) was 8 mg/kg/day and the maternal lowest observed adverse effect level (LOAEL) was 20 mg/kg/day. The developmental NOAEL was greater than or equal to 50 mg/kg/day, the highest dose tested. In a rat developmental toxicity study, the maternal and embryotoxic NOAEL was 100 mg/kg/day, and the maternal and embryotoxic LOAEL was 200 mg/kg/day. The teratological NOAEL was greater than or equal to 400 mg/kg/day, the highest dose tested.

In a 2–generation rat reproduction study, the NOAEL for systemic toxicity was 250 ppm (21 mg/kg/day) on the basis of reduced body weight gain and increased liver and kidney weights. The

NOAEL for reproductive and developmental toxicity was also 250 ppm on the basis of reduced pup weights. No other reproductive or developmental parameters were affected at any treatment level. The highest dose tested was 1,250 ppm (110 mg/kg/day).

4. *Subchronic toxicity*. In 90–day rat studies, the NOAEL was determined to be 500 ppm in the diet (44 mg/kg/day), and the LOAEL was based upon increased liver weights in both sexes and centrilobular hepatocyte enlargement in males. Similar effects, as well as an increase in blood cholesterol concentration, were observed in 90–day mouse studies, and the NOAEL was 15 mg/kg/day.

5. *Chronic toxicity*. EPA has established the reference dose (RfD) for dicloran at 0.025 mg/kg/day. The RfD is based on a 2–year dog feeding study with a NOAEL of 2.5 mg/kg/day and an uncertainty factor of 100. The effect of concern was increased liver weight and histological changes in hepatocytes. In an 80–week mouse study, dicloran was not carcinogenic when administered at dose levels up to 600 ppm (103 mg/kg/day). Hepatotoxicity indicated this to be the approximate maximum tolerated dose (MTD). In a 2–year rat study, dicloran was not carcinogenic when administered at 1,000 ppm (59 mg/kg/day for males and 71 mg/kg/day for females).

6. *Animal metabolism*. Dicloran is rapidly metabolized and excreted by rats, goats and hens. Numerous metabolites derived by reduction, acetylation, hydroxylation, deamination and dechlorination were observed.

7. *Endocrine disruption*. Developmental toxicity studies in rats and rabbits and a reproduction study in rats gave no indication of any effects on endocrine function related to development and reproduction. Subchronic and chronic treatment did not induce any morphological changes in endocrine organs and tissues.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Novigen Sciences' DEEM version 7.62 software was used to perform a worst-case analysis of the proposed action. In a theoretical maximum residue concentration (TMRC) analysis it was assumed that dicloran is used on 100% of the acreage of the currently registered crops, lettuce and endive, and that residues on these crops are equal to the tolerance levels. These assumptions were then applied to all of the crops in the leafy greens subgroup (except spinach), and the two cases were compared. It was found that the proposed tolerance for the leafy greens subgroup (except spinach) would increase the presumed exposure from 9.7% of the RfD to 9.9% for the general population. In the presumably most heavily exposed population subgroup, nursing females, exposure would increase from 11.8% to 11.9% of the RfD. Presumed exposure for children ages 1–6 would increase from 7.5% to 7.9%, and the presumed exposure for children ages 7–12 would increase from 9.0% to 9.2% of the RfD. The presumed exposure of infants was no more than 0.2% of the RfD for any scenario.

No developmental or reproductive effects have been observed which indicate special perinatal sensitivity. Therefore, an analysis of acute exposure has not been conducted.

ii. *Drinking water*. Dicloran has no aquatic uses. Dicloran was not reported in the Agency's survey of pesticides in ground water from 1971–1991, nor in the Agency's 1988–1990 survey of pesticides in drinking water wells. The compound has not been reported in surface water. A small scale prospective ground water study suggests that the average residue in ground water is well below 0.001 ppm. The Agency has not conducted a detailed analysis of potential exposure to dicloran via drinking water; however, Gowan Company believes that chronic exposure from this source is very small.

2. *Non-dietary exposure*. Dicloran has no aquatic, lawn, turf or residential uses.

D. Cumulative Effects

At this time the Agency has not reviewed available information concerning the potentially cumulative effects of dicloran and other substances that may have a common mechanism of toxicity. For purposes of this petition only, Gowan Company is considering only the potential risks of dicloran in its aggregate exposure.

E. Safety Determination

1. *U.S. population*. In the TMRC analysis described in section C above, it was concluded that the proposed action would increase the chronic dietary exposure to dicloran by no more than 0.2% of the RfD for the general population. Exposure from drinking water and all other routes is expected to be negligible. In the TMRC analysis described in section C above, it was concluded that the proposed action would increase the chronic dietary exposure to dicloran by no more than 0.2% of the RfD for the general population. Exposure from drinking water and all other routes is expected to be negligible.

2. *Infants and children*. It was concluded that the proposed action would increase the chronic dietary exposure of infants by no more than 0.1% of the RfD, of children ages 1–6 by no more than 0.4%, and of children ages 7–12 by no more than 0.2%.

In assessing the potential for additional sensitivity of infants and children to residues of dicloran, EPA considers data from developmental toxicity studies in the rat and rabbit and reproduction studies in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

No developmental effects have been observed with dicloran. The lowest embryotoxic NOAEL in these studies was 100 mg/kg/day, compared to a chronic NOAEL of 2.5 mg/kg/day. There is no indication of special perinatal sensitivity in the absence of maternal toxicity and thus no suggestion of special sensitivity of infants and children. Gowan Company concluded that there is a reasonable certainty of no harm to infants and children from aggregate exposure to dicloran residues.

F. International Tolerances

Codex and Canadian maximum residue levels of 10 ppm, identical to the U.S. tolerance level, have been established for lettuce, which is the major crop in this crop subgroup. Dicloran is not registered on a leafy vegetable in Mexico.

[FR Doc. 01–10809 Filed 5–1–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–992; FRL–6762–8]

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.