

Dated: October 3, 2001.

Richard D. Schmitt,

Associate Director, Information Resources and Services Division, Office of Pesticide Programs.

[FR Doc. 01-26268 Filed 10-23-01; 8:45 a.m.]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[PF-1045; FRL-6802-5]

Notice of Filing a Pesticide Petition to Establish a Tolerance for 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-1045, must be received on or before November 23, 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-1045 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-6224; e-mail address: miller.joanne@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	Crop production Animal production

Categories	NAICS codes	Examples of potentially affected entities
	311 32532	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 homepage at <http://www.epa.gov/>. To access this document, on the homepage 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-1045. 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-1045 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-1045. 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: October 5, 2001.

Peter Caulkins,

Acting 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 petitioners. 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.

Industry Task Force

PP 4E3060

EPA has received a pesticide petition (4E3060) from Industry Task Force II on 2,4-D Research Data, McKenna and Cuneo, 1900 K Street, NW., Washington, DC 20006-1108 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 extending for 3 years, until December 31, 2004, the time-limited tolerance for residues of 2,4-dichlorophenoxyacetic acid (2,4-D) in or on the raw agricultural commodity soybeans at 0.02 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant and animal metabolism.* The nature of the residue in plants is adequately understood. Acceptable wheat, lemon, and potato metabolism studies have been submitted. The nature of the residue in animals is adequately understood based upon acceptable ruminant and poultry metabolism studies submitted.

2. *Analytical method.* The residue field tests on soybeans used a gas chromatography (GC) method with electron capture detection (ECD), EN-CAS Method ENC-2/93. This GC/ECD method is adequate for determining residues in or on soybeans with a limit of quantitation (LOQ) of 0.01 ppm.

3. *Magnitude of residues.* In 27 tests on soybeans conducted in Arkansas, Illinois, Louisiana, Missouri, and Tennessee, residues of 2,4-D were nondetectable (<0.01 ppm) in/on all samples of forage and seeds from soybeans treated with a preplant application of 2,4-D (acid, ester, or amine) at 0.5, 1.25, and 2.75 lb active ingredient per acre at 1x, 2.5x, and 5.5x

rates. Residues of 2,4-D were also nondetectable (<0.01 ppm) in/on 21 of 27 hay samples from the same tests. Hay samples with detectable residues of 0.01-0.04 ppm only came from 2.5x and 5.5x applications of the 2,4-D 2-ethylhexyl ester (2-EHE). Since the label restriction against feeding/grazing soybean forage and hay is not proposed for deletion at this time, no tolerances are necessary for these feed items. Since data from the 5.5x application demonstrate that 2,4-D residues on soybean seeds are nondetectable or >0.05 ppm, a soybean processing study is not required. Based on the residue data for seeds from soybeans, a tolerance of 0.02 ppm in or on the raw agricultural commodity soybeans is appropriate.

B. Toxicological Profile

1. *Acute toxicity.* The oral LD₅₀ of 2,4-D acid is 699 mg/kg in the rat. The dermal LD₅₀ in the rabbit is >2,000 mg/kg. The acute inhalation LC₅₀ in the rat is >1.8 mg/liter. A primary eye irritation study in the rabbit showed severe irritation. A dermal irritation study in the rabbit showed moderate irritation. A dermal sensitization study in the guinea pig showed no skin sensitization. An acute neurotoxicity study in the rat produced a no observed adverse effect level (NOAEL) of 227 milligram/kilograms (mg/kg) for systemic toxicity and a neurobehavioral NOAEL of 67 mg/kg with a lowest observed adverse effect level (LOAEL) of 227 mg/kg.

2. *Genotoxicity.* Mutagenicity studies including gene mutation, chromosomal aberrations, and direct DNA damage tests were negative for mutagenic effects.

3. *Reproductive and developmental toxicity.* A 2-generation reproduction study was conducted in rats with NOAELs for parental and developmental toxicity of 5 mg/kg/day. The LOAELs for this study are established at 20 mg/kg/day based on reductions in body weight gain in F₀ and F_{2b} pups, and reduction in pup weight at birth and during lactation. A teratology study in rabbits given gavage doses at 0, 10, 30, and 90 mg/kg on days 6 through 18 of gestation was negative for developmental toxicity at all doses tested. A teratology study in rats given gavage doses at 0, 8, 25, and 75 mg/kg on days 6 through 15 of gestation showed maternal toxicity only at 75 mg/kg. A NOAEL for fetotoxicity was established at 25 mg/kg/day based on delayed ossification at the 75 mg/kg dose level. The effects on pups occurred in the presence of parental toxicity.

4. *Subchronic toxicity.* A subchronic dietary study was conducted with mice

fed diets containing 0, 1, 15, 100, and 300 mg/kg/day with a NOAEL of 15 mg/kg/day. The (LOAEL) was established at 100 mg/kg/day based on decreased glucose and thyroxine levels, increases in absolute and relative kidney weights, and histopathological lesions in the liver and kidneys. A 90-day dietary study in rats fed diets containing 0, 1, 15, 100, or 300 mg/kg/day resulted in a NOAEL of 15 mg/kg/day and an LOAEL of 100 mg/kg/day. The LOAEL was based on decreases in body weight and food consumption, alteration in clinical pathology, changes in organ weights, and histopathological lesions in the kidney, liver, and adrenal glands of both sexes of rats. A 90-day feeding study was conducted in dogs fed diets containing 0, 0.3, 1, 3, and 10 mg/kg/day with a NOAEL of 1 mg/kg/day. The LOAEL was established at 3 mg/kg/day based on histopathological changes in the kidneys of male dogs.

5. *Chronic toxicity.* A 1-year dietary study was conducted in the dog using doses of 0, 1, 5, and 7.5 mg/kg/day. The NOAEL was 1 mg/kg/day and the LOAEL was 5 mg/kg/day based on clinical chemistry changes and histopathological lesions in the liver and kidney. A 2-year feeding/carcinogenicity study was conducted in mice fed diets containing 0, 1, 15, and 45 mg/kg/day with a NOAEL of 1 mg/kg/day. The systemic LOAEL was established at 15 mg/kg/day based on increased kidney and adrenal weights and homogeneity of renal tubular epithelium due to cytoplasmic vacuoles. No carcinogenic effects were observed under the conditions of the study at any dosage level tested.

A second 2-year oncogenicity study was conducted in mice fed diets containing 0, 5, 62.5, and 125 mg/kg/day (males) and 0, 5, 150, and 300 mg/kg/day (females). The NOAEL was 5 mg/kg/day and LOAEL was 62.5 (M) and 150 (F) mg/kg/day based on increases in absolute and/or relative kidney weights and histopathological lesions in the kidneys. No treatment-related oncogenicity was observed.

A 2-year feeding/carcinogenicity study was conducted in rats fed diets containing 0, 1, 15, and 45 mg/kg/day with a NOAEL of 1 mg/kg/day. Although there appeared to be a slight treatment-related incidence of benign brain tumors (astrocytomas) in male rats fed diets containing 45 mg/kg/day, two different statistical evaluations found no strong statistical evidence of carcinogenicity in male rats. There were no carcinogenic effects observed in female rats.

A second 2-year feeding/carcinogenicity study was conducted in rats fed diets containing 0, 5, 75, and

150 mg/kg/day. The NOAEL was 5 mg/kg/day and the LOAEL was 75 mg/kg/day based on decreased body weight, body weight gain, and food consumption; clinical chemistry changes; organ weight changes and histopathological lesions. No treatment-related carcinogenic effects or increased incidences of astrocytomas were observed.

6. *Animal metabolism.* The metabolism of phenyl ring labeled ^{14}C -2,4-D was studied in the rat following a single intravenous or oral dose of approximately 1 mg/kg/day. At 48 hours after treatment, recovery of radioactivity in urine was in excess of 98%. Parent 2,4-D was the major metabolite (72.9% to 90.5%) found in the urine.

7. *Metabolite toxicology.* Because 2,4-D is rapidly excreted without significant metabolism, the toxicology data on the parent compound adequately represents metabolite toxicology.

8. *Endocrine disruption.* Although tests explicitly designed to evaluate the potential endocrine effects of 2,4-D have not been conducted, a large and diverse battery of toxicology studies is available including acute, subchronic, chronic, reproductive, and developmental toxicity tests. The results of these studies do not provide a pattern of effects suggestive of endocrine modulated toxicity.

C. Aggregate Exposure

1. *Dietary exposure.* Residues are below the limit of quantification (LOQ = 0.01 ppm) in soybeans. Tolerances have been established (40 CFR 180.142) for residues of 2,4-D as the acid or various of its salts and esters, in or on a variety of raw agricultural commodities. In addition, there are also tolerances for 2,4-D for meat, milk, and eggs.

2. *Drinking water.* 2,4-D is soluble in water. The average field half-life is 10 days. The chemical is potentially mobile, but rapid degradation in soil and removal by plant uptake minimizes leaching. A Maximum Contaminant Level (MCL) of 0.07 mg/L has been established. In addition, the following Health Advisories have been established: For a 10-kg child, a range of 1 mg/L from 1-day exposure to 0.1 mg/L for longer-term exposure up to 7 years; for a 70 kg adult, a range of 0.4 mg/L for longer-term exposure to 0.07 mg/L for lifetime exposure.

3. *Non-dietary exposure.* 2,4-D is currently registered for use on the following residential non-food sites: Ornamental turf, lawns, and grasses, golf course turf, recreational areas, and several other indoor and outdoor uses. 2,4-D is a commonly-used pesticide in

non-agricultural settings. There are chemical-specific and site-specific data available to determine the potential risks associated with residential exposures from the registered uses of 2,4-D. Dislodgeable residues taken from ten 2,4-D turf transferable residue studies showed low dislodgeable percent of application, 0.9% at 1 hour, 0.8% at 8 hours and 0.7% at 24 hours following applications. No detectable residues were found in urine samples supplied by volunteers exposed to sprayed turf 24 hours following application. Intermediate-term postapplication exposure is thus not expected.

D. Cumulative Effects

There are no available data to determine whether 2,4-D has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 2,4-D does not appear to produce a toxic metabolite produced by other substances.

E. Safety Determination

1. *U.S. population.* For chronic dietary exposure, EPA has established the Reference Dose (RfD) for 2,4-D at 0.01 milligrams/kilogram/day (mg/kg/day). This RfD is based on a 1-year oral toxicity study in dogs with a NOAEL of 1 mg/kg/day and an uncertainty factor of 100. In the most recent final rule establishing tolerances for 2,4-D (time-limited tolerance in soybeans at 64 FR 11792 on March 10, 1999), EPA calculated aggregate risks for the existing uses of 2,4-D at that time (including soybeans and all other existing uses). Since those uses have not changed in the interim, it is appropriate to utilize the same calculations to support extension of the time-limited tolerance in or on soybeans. Chronic dietary exposure estimates (from Dietary Exposure Evaluation Model) used mean consumption (3 day average) and anticipated or tolerance-level residues for all commodities. Exposure estimates used 25.6% of the RfD for the general U.S. population (48 states) and 49.2% of the RfD for the most exposed population of non-nursing infants (less than 1 years old). Despite the potential for exposure to 2,4-D in drinking water and from non-dietary, non-occupational exposure, EPA did not expect the aggregate exposure to exceed 100% of the RfD.

For acute dietary exposure, the NOAEL of 67 mg/kg/day from the rat acute neurotoxicity study should be used for risk assessment. As

neurotoxicity is the effect of concern, the acute dietary risk assessment should evaluate acute dietary risk to all population subgroups. Again, relying upon the EPA calculations underlying the most recent final rule establishing tolerances for 2,4-D cited above, which included soybeans and all other existing uses, EPA calculated acute aggregate risk taking into account anticipated residues or tolerance level residues on all treated crops, which is a significant over estimation of dietary exposure. For the U.S. population, the acute dietary margin of exposure (MOE) is 321 and it is 399 for females 13+ years. These figures do not exceed EPA's level of concern for acute dietary exposure.

Regarding dietary cancer risk assessment, EPA's Cancer Peer Review Committee has classified 2,4-D as a Group D chemical (not classifiable as to human carcinogenicity) on the basis that, the evidence is inadequate and cannot be interpreted as showing either the presence or absence of a carcinogenic effect.

2. *Infants and children.* The data base on 2,4-D relative to prenatal and postnatal toxicity is complete with respect to current data requirements. Since the developmental NOAELs for rats and rabbits are 25-fold greater and 90-fold greater, respectively, than the RfD NOAEL of 1 mg/kg/day in the 17-year oral toxicity study in dogs, an additional uncertainty factor to protect infants and children is not warranted.

Using conservative EPA calculations underlying the most recent final rule establishing tolerances for 2,4-D cited above, which included soybeans and all other existing uses, aggregate acute MOEs for exposure to 2,4-D from food are 214 for infants less than 1 years old and 399 for females 13 and older. The maximum estimated concentrations of 2,4-D in surface and ground water are less than EPA's Drinking Water Level of Comparison (DWLOC) figures for 2,4-D as a contribution to acute aggregate exposure. EPA concluded with reasonable certainty that residues of 2,4-D in drinking water do not contribute significantly to the aggregate acute human health risk.

Using the same conservative assumptions described earlier to estimate chronic risk from aggregate chronic exposure to 2,4-D from food, 11.4% of the RfD is utilized for nursing infants less than 1 years old up to 49.2% of the RfD for non-nursing infants less than 1 years old. Further refinement using additional anticipated residue values in crops and percent crop-treated information would result in lower chronic dietary (food) exposure estimates, thus reducing the aggregate

risk estimate. Despite the potential for exposure to 2,4-D in drinking water and from non-dietary, non-occupational exposure, EPA concluded that it did not expect the aggregate exposure to exceed 100% of the RfD.

F. International Tolerances

There are no Codex, Canadian, or Mexican maximum residue limits for use of 2,4-D on soybeans.

[FR Doc. 01-26534 Filed 10-23-01; 8:45 am]

BILLING CODE 6560-S

EXPORT-IMPORT BANK OF THE UNITED STATES

Notice of Open Special Meeting of the Sub-Saharan Africa Advisory Committee (SAAC) of the Export-Import Bank of the United States (Export-Import Bank)

SUMMARY: The Sub-Saharan Africa Advisory Committee was established by Pub. L. 105-121, November 26, 1997, to advise the Board of Directors on the development and implementation of policies and programs designed to support the expansion of the Bank's financial commitments in Sub-Saharan Africa under the loan, guarantee and insurance programs of the Bank. Further, the committee shall make recommendations on how the Bank can facilitate greater support by U. S. commercial banks for trade with Sub-Saharan Africa.

Time and Place: Wednesday, November 7, 2001, at 9:30 a.m. to 12 p.m. The meeting will be held at the Export-Import Bank in room 1143, 811 Vermont Avenue, NW, Washington, DC 20571.

Agenda: This meeting will focus on improving deal flow for transactions in sub-Saharan Africa. SAAC members and the Bank staff will discuss opportunities in various markets and sectors and will also discuss actions that the Bank can take to increase transactions.

Public Participation: The meeting will be open to public participation, and the last 10 minutes will be set aside for oral questions or comments. Members of the public may also file written statement(s) before or after the meeting. If any person wishes auxiliary aids (such as a sign language interpreter) or other special accommodations, please contact, prior to November 1, 2001, Teri Stumpf, Room 1215, 811 Vermont Avenue, NW, Washington, DC 20571, voice: (202) 565-3502 or TDD (202) 565-3377.

FOR FURTHER INFORMATION CONTACT: For further information, contact Teri Stumpf, Room 1215, 811 Vermont

Avenue, NW, Washington, DC 20571, (202) 565-3502.

Peter B. Saba,

General Counsel.

[FR Doc. 01-26786 Filed 10-23-01; 8:45 am]

BILLING CODE 6690-01-M

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Revocations

The Federal Maritime Commission hereby gives notice that the following Ocean Transportation Intermediary licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, effective on the corresponding date shown below:

License Number: 4300F.

Name: American Intercargo Express Inc.

Address: One World Trade Center, Suite 4667, New York, NY 10048.

Date Revoked: September 13, 2001.

Reason: Failed to maintain a valid bond.

License Number: 15644N.

Name: Amerilines, Inc.—New York.

Address: 7 Dey Street, Suite 1501, New York, NY 10007.

Date Revoked: September 28, 2001.

Reason: Failed to maintain a valid bond.

License Number: 11238N.

Name: Arrow Cargo Express, Inc.

Address: 2254-B Landmeier Road, Elk Grove Village, IL 60007.

Date Revoked: September 26, 2001.

Reason: Failed to maintain a valid bond.

License Number: 16341N.

Name: Dit (USA), Inc.

Address: 1805 W. Hovey Ave., Suite B, Normal, IL 61761.

Date Revoked: August 17, 2001.

Reason: Surrendered license voluntarily.

License Number: 2430F.

Name: Emigdio S. Ledesma dba Jack Ledesma International Forwarder.

Address: 729 83rd Avenue North, Suite 204, St. Petersburg, FL 33702.

Date Revoked: September 20, 2001.

Reason: Failed to maintain a valid bond.

License Number: 2338NF.

Name: Kamden International Shipping, Inc.

Address: 179-02 150th Avenue, Jamaica, NY 11434.

Date Revoked: September 23, 2001.

Reason: Failed to maintain a valid bond.