ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0378; FRL–7688–2]

2,4-D; Notice of Filing a Pesticide Petition to Establish a Permanent Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the 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 identification (ID) number OPP–2004–0378, must be received on or before January 14, 2005.

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, EnvironmentalProtection 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 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. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2004–0378. 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, 1801 S. Bell St., 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 in 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 totechnical 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–2004–0378. 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–2004–0378. 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–2004–0378.

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, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2004–0378. 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: November 30, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner 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

PP 4E3060

EPA has received a pesticide petition (4E3060) from the Industry Task Force II on 2,4-D Research Data (Task Force) and its registrant members and affiliates, 1900 K St., NW., Washington, DC 20006 on behalf of The Interregional Research Project Number 4 (IR-4) 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 to remove the expiration date of December 31, 2004 for 2,4-D in or on the raw agricultural commodity soybean seed at 0.02 parts per million (ppm) (40 CFR 180.142(a)(11)) (March 8, 2002, 67 FR 10622). 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 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), ENCAS 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 part per million (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 lbs active ingredient per acre at lX, 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 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 soybeans, tolerances of 0.02, 2.0, and 0.02 ppm in or on the raw agricultural commodities soybean seed, hay, and forage are appropriate.

B. Toxicological Profile

1. *Acute toxicity*. The oral lethal dose $(LD)_{50}$ of 2,4-D acid is 699 milligrams/kilogram (mg/kg) in the rat. The dermal LD_{50} in the rabbit is >2,000 mg/kg. The acute inhalation lethal concentration $(LC)_{50}$ in the rat is >1.8 milligrams/liter (mg/l). 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 mg/kg for systemic toxicity and a neurobehavioral NOAEL of 67 mg/kgwith a lowest observed adverse effect level (LOAEL) of 227 mg/kg.

2. *Genotoxicty*. Mutagenicity studies including gene mutation, chromosomal aberrations, and direct DNA damage tests were negative for mutagenic effects. 2,4-D acid has been evaluated extensively in open literature in a range of *in vivo* and *in vitro* assays that have included tests with human cells. Overall, the pattern of responses observed in both *in vivo* and *in vitro* tests indicates that 2,4-D acid was not mutagenic, although some cytogenetic effects were observed.

3. *Reproductive and developmental toxicity*. A two-generation reproduction study was conducted in rats with NOAELs for parental and offspring toxicity of 5 milligrams/kilograms/day (mg/kg/day). The LOAELs for this study are established at 20 mg/kg/day based on decreased female body weight/body weight gain (F1), male renal tubule alteration (F0 and F1), and decreased pup body weight (F1b). 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 alldoses 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, which is above the renal clearance threshold for 2,4-D. A NOAEL for fetotoxicity was established at 25 mg/kg/day based on skeletal abnormalities and variations 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 decreased body weight/body weight gain and food consumption (males), alterations in clinical chemistry parameters increased blood urea nitrogren (both sexes), creatinine (both sexes), and decreased testis weight (males).

5. *Chronic toxicity*. Previously, the 2,4-D chronic reference dose was based on the chronic dog study. More recently, the Hazard Identification Assessment Review Committee (HIARC) chose to use the rat as the more relevant species for risk assessment. Use of the dog as the basis for regulation exaggerates the apparent severity of effects anticipated because of the limited renal capacity of dogs to excrete organic acids. Points of consideration included: The dog has a decreased clearance relative to humans, rats, mice, and other species. The decreased clearance results in higher blood levels in the dog relative to those found in the rat and consequently, effects are seen at lower dose levels in the dog than in the rat. The half-life of elimination for dogs is significantly longer than for all other species considered. Dogs exhibited half-lives of 31 to 106 hours for doses of 1 to 5 mg/kg. In other species (mice, rats, pigs, cats, and humans), elimination half-lives ranged from 0.75 to 11.6 hours for similar doses. The difference in the elimination pattern among dogs and other mammalian species persuaded HIARC that the rat was a better predictor than the dog of the potential toxicity of 2,4-D to human.

A 2–year oncogenicity 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 treatment-related increase in kidney weights in both sexes and microscopic renal lesions in males. There was no treatment-related increase in the incidence of any tumor type. A subsequent 2–year oncogenicity study in mice with a NOAEL of 5 mg/kg/day demonstrated that the NOAEL of 1 mg/kg/day in this earlier study was an artifact of dose selection.

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 (males) and 150 (females) mg/kg/day based on an increased absolute and/or relative kidney weights and an increased incidence of renal microscopic lesions. There was no treatment-related increase in the incidence of any tumor type.

A 2–year feeding/oncogenicity 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 gain (females) and food consumption (females), alterations in hematology decreased red blood cells (females), hemoglobin (females), platelets (both sexes) and clinical chemistry parameters increased creatinine (both sexes), alanine and aspartate aminotransferase (males), alkaline phosphatase (both sexes), decreased T4 (both sexes), glucose (females), cholesterol (both sexes), and triglycerides (females), increased thyroid weights (both sexes at study termination), decreased testes and ovarian weights, and microscopic lesions in the lungs (females). At the high-dose level, there were microscopic lesions in the eyes, liver, adipose tissue, and lungs. There was no treatment-related increase in the incidence of any tumor.

6. *Animal metabolism*. The metabolism of phenyl ring labeled 14C-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 94%. 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, large and diverse batteries of toxicology studies are available including acute, subchronic, chronic, reproductive, and developmental toxicity tests. The thyroid effects seen in the subchronic (decreases in T4, follicular cell hypertrophy) and chronic (decreases in T4, increase in thyroid weights) toxicity study in rats occurred only at high doses, which were at or above the threshold of renal clearance. These effects were seen in the presence of other systemic (liver or kidney) toxicity, and there was no evidence of thyroid toxicity in dogs. No evidence of endocrine disruptions were seen in the appropriate parameters that evaluated this effect in the two-generation reproduction study.

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.

i. *Food*. The Agency has conducted an extensive assessment of the aggregate exposure. Results are reported in the **Federal Register** of March 8, 2002 (FR 67 10622) (FRL–6827–1). The Agency found that acute dietary exposure from food to 2,4-D will occupy 7.3% of the acute population adjusted dose (aPAD) for the U.S. population, 12% of the aPAD for females 13 years and older, 9.4% of the aPAD for infants less than 1 year old, 12% of the aPAD for children 1–6 years old, and 8.8% of the aPAD for children 7–12 years old. The Agency found that chronic dietary exposure to 2,4-D from food will utilize24% of the chronic population adjusted dose (cPAD) for the U.S. population, 20% for females 13 years and older, 19% of the cPAD for infants less than 1 year old, 46% of the cPAD for children 1–6 years old, and 36% of the cPAD for children 7–12 years old.

ii. *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.

2. *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 10 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 post-application exposure is thus not expected.

D. Cumulative Effects

A cumulative risk assessment cannot be performed as part of a human health risk assessment because EPA has not yet made a determination as to which compounds to which humans may be exposed, if any, have a common mechanism of toxicity. 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 RfD for 2,4-D at 0.005 mg/kg/day. This RfD is based on a 2–year dietary toxicity study in rats with a NOAEL of 5 mg/kg/day and an uncertainty factor of 1,000. In the most recent revised HED human health risk assessment, EPA used tolerance-level exposure values for most commodities, and averages of field trial data, and processing study factors for small grains, citrus, and sugarcane sugar, and molasses. EPA concluded that for food consumption only, chronic dietary (food only) risks calculated using the Dietary Exposure Evaluation Model (DEEM™) software consumed 2.5–6.9% of the cPAD (2.5–6.7% cPAD using Lifeline). Risk to the general U.S. population was 3.4% of the cPAD (3.2% cPAD using Lifeline). 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 cPAD.

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 June 2, 2004, revised HED human health risk assessment, EPA concluded that risk to the general U.S. population was 17% of the aPAD using both DEEM™ and Lifeline.

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 database on 2,4-D relative to prenatal and postnatal toxicity is complete with respect to current data requirements. In its most recent evaluations, EPA has

determined that, based on the 2,4-D database summarized above, no special FQPA safety factor is needed (1X) since there are no residual uncertainties for prenatal and/or postnatal toxicity. Chronic dietary risk to children 1–2 years of age, the most highly exposed population subgroup, was 6.9% of the cPAD (6.7% cPAD using Lifeline). For acute dietary risk, the most highly exposed population subgroup using both DEEM™ and Lifeline was children 1–2 years of age; risks were 33% and 30% of the aPAD, respectively.

F. International Tolerances

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

[FR Doc. 04–27173 Filed 12–14–04; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted to OMB for Review and Approval

December 8, 2004.

SUMMARY: The Federal Communications Commissions, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before January 14, 2005. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC 20554 or via the Internet to *Cathy.Williams@fcc.gov* or Kristy L. LaLonde, Office of Management and Budget (OMB), Room 10236 NEOB, Washington, DC 20503, (202) 395–3087 or via the Internet at *Kristy_L._LaLonde@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information or copy of the information collection(s) contact Cathy Williams at (202) 418–2918 or via the Internet at *Cathy.Williams@fcc.gov*.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0095.

Title: Multi-Channel Video Programming Distributors Annual Employment Report, FCC Form 395–A.

Form Number: FCC Form 395–A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 2,500.

Estimated Time Per Response: 53 minutes (0.88 hours).

Frequency of Response: Recordkeeping requirement; Annual reporting requirement; Once every five years.

Total Annual Burden: 2,200 hours.

Total Annual Cost: None.

Privacy Impact Assessment: No impact(s).

Needs and Uses: FCC Form 395–A, ''The Multi-Channel Video Programming Distributor Annual Employment Report,'' is a data collection device used to assess industry employment trends and provide reports to Congress. The report identifies employees by gender and race/ethnicity in fifteen job categories. FCC Form 395–A contains a grid which collects data on full and part-time employees and requests a list of employees by job title, indicating the job category and full or part-time status of the position. Every cable entity with 6 or more full-time employees and all Satellite Master Antenna Television Systems (SMATV) serving 50 or more subscribers and having 6 or more full-time employees must complete FCC Form 395–A in its entirety and file it by September 30 each year. However, cable entities with 5 or fewer full-time employees are not required to file but if they do, they need to complete and file only Sections I, II and VIII of the FCC Form 395–A, and thereafter need not file again unless their employment increases. In addition, cable entities with 6 or more full-time employees will file a Supplemental Investigation Sheet once every 5 years.

On June 4, 2004, the FCC released the Third Report and Order and Fourth Notice of Proposed Rulemaking (3rd R&O), In the Matter of Review of Commission's Broadcast and Cable Equal Employment Opportunity Rules and Policies, MM Docket No. 98–204, FCC 04–103, in which it considers issues relating to the Annual Employment Report forms, including FCC Form 395–A, ''The Multi-Channel Video Programming Distributor Annual Employment Report.'' In the 3rd R&O, the Commission is adopting revised rules for MVPDs to file FCC Form 395–A, which cable and other MVPDs will use to file annual employment reports. The intent of this 3rd R&O is to update rules for MVPDs to file Form 395–A consistent with new rules adopted in the 2nd R&O. The intent of the Fourth Notice of Proposed Rulemaking is to provide time for cable and other MVPDs and the public to address the issue of whether the Commission should keep these forms confidential after they are filed. With the effective date of the rule revisions adopted in the 3rd R&O, MVPDs and broadcasters must start keeping records of their employees so they can prepare their annual employment reports that were due to be filed on September 30, 2004.

OMB Control Number: 3060–0171.

Title: Section 73.1125, Station Main Studio Location.

Form Number: Not applicable.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 72.

Estimated Time Per Response: 0.5–2 hours.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 135 hours.

Total Annual Cost: $87,780.00.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On March 14, 2002, the Commission released an Order, Establishment of the Media Bureau and Other Organizational Changes, DA No. 02–577, the Commission amended 47 CFR 73.1125(d) to reflect the reorganization of the existing Cable Services and Mass Media Bureaus into a new Media Bureau. Section 73.1125(d) requires licensees to receive written authority to locate a main studio outside the locations specified in paragraph (a) or (c) of this rule section for the first time must be obtained from the Audio Division, Media Bureau for AM and FM stations, or the Video Division for TV