ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–5482–8]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared July 7, 1997 Through July 11, 1997 pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the OFFICE OF FEDERAL ACTIVITIES AT (202) 564–7167. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 4, 1997 (62 FR 16154).

Draft EISs

ERP No. D–BOP–E80001–KY Rating EC2, United States Penitentiary Martin County, Construction and Operation, Possible Sites, Bizwell and Honey Branch Sites, located in Martin and Johnson Counties, KY.

Summary: EPA expressed environmental concerns due to potential wetland impacts and requested addition information on this issues.

Final EISs

ERP No. F–AFS–L65263–ID, Targhee National Forest, Forest Plan Revision, Bonneville, Butte, Clark, Fremont, Jefferson, Lemhi, Madison and Teton Counties, ID and Lincoln and Teton Counties, WY.

Summary: Review of the Final EIS was not deemed necessary. No formal comment letter was sent to the preparing agency.

ERP No. F–FAA–C51016–00, John F. Kennedy International Airports, Light Rail System, Implementation of Automated Guideway Transit System by the Port Authority Program, Funding, Airport Layout Plan Approval, COE Section 10 and 404 Permits, NY and NJ.

Summary: EPA had no objection to the project as proposed, therefore the project would not result in significant environmental impacts.

ERP No. FS–NOA–E64007–00, Fishery Management Plan (FMP) for the Shrimp Fishery of the Gulf of Mexico portions of the Exclusive Economic Zone (EEZ), Amendment 9 Concerning Reduction of Unwanted Bycatch of Juvenile Red Snapper with Ancillary Benefits to Other Finfish Species, adjacent to State Waters of TX, LA, MS, AL and FL.

Summary: EPA had no objection to the action as proposed. EPA stated its support for mandatory use of Bycatch Reduction Devices.

Other

ERP No. LD–AFS–L61209–00 Rating LO, Wallowa-Whitman National Forest, Wild and Scenic River Study, Eight Rivers for Suitability and inclusion in the National Wild and Scenic Rivers System, Baker, Union and Umatilla Counties, OR and Adams and Idaho Counties, ID.

Summary: EPA's abbreviated review has revealed no concerns on this project.

Dated: July 29, 1997.

B. Katherine Biggs,

Associate Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 97–20381 Filed 7–31–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[PF–751; FRL–5732–4]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF–751, must be received on or before September 2, 1997.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7506C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Mary Waller, Acting (PM 21), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 265, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 308–9354; e-mail: waller.mary@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–751] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PF–751] and appropriate petition number. Electronic

comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 22, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them 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.

1. AgrEvo USA Company

PP 4E4384

EPA has received a pesticide petition (PP 4E4384)from AgrEvo USA Company, Little Falls Centre One, 2711 Centerville Rd., Wilmington, DE 19808, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of the fungicide (*N*-4,6-dimethylpyrimidin-2-yl) aniline expressed as pyrimethanil in or on the raw agricultural commodity (RAC) grapes at 5.0 ppm, and the processed food, raisins at 8.0 ppm.

A. Residue Chemistry

1. *Metabolism*. Numerous studies have been conducted to evaluate the absorption, distribution, metabolism and/or excretion of pyrimethanil in rats. These studies indicate that pyrimethanil is rapidly absorbed, metabolized and excreted primarily through the kidneys; rats given an oral dose of 1,000 mg/kg excrete over 95% of compound related products in urine within 6 to 8 hours, studies in other species including the dog and mouse show similar rapid and quantitative excretion profiles. There is no evidence of any significant accumulation in tissues on repeat dosing in rats.

2. *Analytical method*. The nature of the residue in grapes is adequately understood. The residue of concern is the parent compound only. The proposed analytical method for determining residues of pyrimethanil is high-pressure liquid chromatography, with a UV detector. This method has adequate accuracy, precision and sensitivity for this purpose. This method has been confirmed through an independent laboratory validation.

3. *Magnitude of residues*. Field residue and processing studies were submitted from trials from the various countries of proposed use including France, Germany, Italy, South Africa, Spain and Greece. These data demonstrate that the proposed tolerance of 5.0 ppm will be adequate to cover the residues in grapes or wine. Processing data show that pyrimethanil residues in wine will not exceed the tolerance in the RAC grapes. Data from residue trials in Chile reflecting the proposed use pattern on table grapes also demonstrate that the proposed tolerance of 5.0 ppm is adequate to cover the residues on fresh table grapes. Processing data on raisins indicates that there is a concentration factor of 1.6 and a tolerance of 8.0 ppm is proposed to cover the residues of pyrimethanil in raisins. Residues in juice were determined to be 70% of the residues in fresh grapes; therefore, the tolerance on fresh grapes is sufficient to cover the potential residues of pyrimethanil in grape juice.

B. Toxicological Profile

1. *Acute toxicity*. The acute rat oral LD_{50} of pyrimethanil was 4.15 g/kg in males and 5.97 g/kg in females. The acute rat dermal LD_{50} was $\geqq$ 5.0 g/kg in both sexes. The 4-hour rat inhalation LC_{50} was >1.98 mg/L in males and in females. Pyrimethanil was not irritating to rabbit skin and slightly irritating to the rabbit eyes. Pyrimethanil did not cause skin sensitization in guinea pigs. Based on these data, EPA has classified pyrimethanil as Tox Category III for inhalation and oral toxicity, and Tox Category IV for dermal toxicity, skin and eye irritation.

2. *Genotoxicty*. No evidence of genotoxicity was noted in an extensive battery of *in vitro* and *in vivo* studies. Negative studies determined acceptable by EPA included an Ames Assay (*S. typhimurium*), Gene mutation (*E. coli*), In vivo mouse micronucleus, in-vitro chromosome analysis of cultured human lymphocytes and Unscheduled DNA synthesis.

3. *Reproductive and developmental toxicity*. A developmental toxicity study was conducted in rats. The NOEL s for maternal and developmental effects were determined by the EPA to be 85 mg/kg/day for maternal toxicity and 1,000 mg/kg/day (limit dose) for developmental effects. There were no teratogenetic or embryotoxic effects in fetuses at 1,000 mg/kg/day.

A developmental toxicity study in rabbits with a maternal NOEL of 7 mg/kg/day. The developmental NOEL was determined by the EPA to be 45 mg/kg/day.

A 2-generation rat reproduction study was determined by the EPA to have a reproductive and developmental NOEL of 23.1 mg/kg/day in males and 27.4 mg/kg/day in females.

4. *Subchronic toxicity*. A 90-day feeding study was conducted in CRL:CD (SD) BR strain rats with a NOEL of 5.4 mg/kg/day.

A 90-day study was conducted in beagle dogs with a NOEL of 6 mg/kg/day and a LOEL of 80mg/kg/day.

5. *Chronic toxicity*. A 12-month dog study was determined by EPA to have a NOEL of 30 mg/kg/day.

A 2-year mouse oncogenicity study in CRL: CD-1 (ICR) BR with a NOEL for systemic effects of 211 and 253 mg/kg/day for males and females, respectively. At doses up to 1,600 ppm there was no evidence of oncogenicity. The EPA concluded that the highest dose did not achieve an MTD, however the EPA Peer Review Committee concluded that the data were sufficient to classify the compound with respect to carcinogenicity at this time.

A combined chronic toxicity/oncogenicity study was conducted in CRL:CD (SD) BR strain rats with a NOEL of 17 and 22 mg/kg/day for males and females, respectively. Findings included increased thyroid follicular cell adenomas in male and female rats. The EPA Peer Review Committee concluded on February 11, 1997 that there was sufficient evidence from the data provided to conclude that the thyroid tumors were a result of disruption of the thyroid-pituitary status.

6. *Endocrine effects*. There is no evidence from the data or chemical structure that pyrimethanil causes endocrine effects other than those already noted for the thyroid-pituitary-liver axis.

C. Aggregate Exposure

Dietary exposure. The aggregate exposure to pyrimethanil is limited to dietary exposure only because no U.S. registrations are being sought. A worst case estimate of the dietary exposure from the tolerance on grapes results in a maximum theoretical exposure of 0.55% of the reference dose for the U.S. population and a worst case estiimate of 1.29% of the ADI for children 1-6 years old. This worst case estimate assumes

that all diets contain grapes and grape products with the maximum theoretical residue. In reality this will not be the case because in commerce, only imported grapes and grape products have the potential for residues. In addition, only a portion of the crop will actually be treated and, under actual use conditions the residue will be much smaller that the residue trials indicate. It can therefore be estimated that the actual exposure to pyrimethanyl in the diet will be less than 0.1% of the ADI, or negligible from a dietary point of view.

D. Cumulative Effects

There is no evidence that the mechanism of toxicity of pyrimethanil shares a common mechanism with any other pesticides. In addition, the dietary exposure in grapes or grape products is negligible and therefore, AgrEvo believes that even if it did share a common mechanism with another product, pyrimethanil would not contribute in a significant way to the overall risk.

E. Safety Determination

1. *U.S. population —Reference dose*. Based upon the results of the oncogenicity studies, genotoxicity studies, structure-activity analysis and studies on the effects of pyrimethanil on the thyroid-pituitary-liver axis, the EPA Peer Review Committee has concluded that pyrimethanil should be classified as a category C with respect to carcinogenicity and that a threshold methodology (MOE) should be considered in conducting the risk assessment. The appropriate reference dose is .3 mg/kg/day based upon the NOEL in the chronic oral dog study with a 100 fold safety factor. This reference dose is adequate to protect infants and children and based upon the data there is no need for an additional safety factor.

2. *Infants and children*. It is proposed that an additional 10X safety factor is not required for pyrimethanil. The toxicology data are complete and there is no evidence of increased sensitivity to young animals. Therefore, a 100X safety factor should be sufficient and protective of the health of adults, infants and children.

F. International Tolerances

At the present time there are no Mexican, Canadian or Codex maximum residue limits for pyrimethanil in or on grapes. Therefore compatibility is not an issue.

2. Griffin Corporation

PP 5F4582

EPA has received a pesticide petition (PP 5F4582) from Griffin Corporation, P.O. Box 1847, 2509 Rocky Ford Road, Valdosta, GA 31603-1847 proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of maneb, mancozeb and their metabolite ethylenethiourea (ETU) in or on the raw agricultural commodity walnuts at 0.05 parts per million (ppm). An adequate analytical method is available for enforcement purposes. 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 metabolism*. Residue tolerances are established for maneb and mancozeb at 40 CFR 180.110 and 40 CFR 180.176, respectively. It is well known that the key metabolite of toxicological concern is ethylenethiourea (ETU). Ethylenebisdithiocarbamate (EBDC), including maneb and mancozeb are not systemic in plants; therefore, EBDC and ETU residues that might be found on walnut nutmeats would then occur as a surface residue transferred at the time of harvesting or shelling operations.

2. *Analytical method*. An adequate analytical method is available for enforcement purposes. The method describes gas chromatographic procedures and appropriate limits of quantitation. In general, maneb and mancozeb residues are measured by digesting the crop component with acid, which converts the EBDC to carbon disulfide. The carbon disulfide residues are measured to determine the level of EBDC residue. ETU residues are measured by extraction from the crop and analysis by high pressure liquid chromatography or by extraction, formation of a derivative, and measurement of the derivative by gas chromatography.

3. *Magnitude of residues*. Residues of maneb and mancozeb in walnut meat samples ranged from just below to just above the limit of quantitation (0.01 ppm). The ETU metabolite was not detected in any samples analyzed (limit of quantitation was 0.01 ppm).

B. Toxicological Profile

1. *Acute toxicity*. Maneb and mancozeb are virtually non-toxic after administration by the oral, dermal and respiratory routes.

i. *Maneb*. The acute oral LD_{50} for rats is 6,750 mg/kg. The acute dermal LD_{50} for rabbits > 2,000 mg/kg and for rats > 5,000 mg/kg. Acute inhalation LC_{50} for rats > 1.30 mg/l. Maneb is classified as a slight irritant to skin and eye irritation in rabbits clears in 7 days. Maneb has been classified as a sensitizer in guinea pigs.

ii. *Mancozeb*. The acute oral LD_{50} in mice and rats is >5,000 mg/kg. The acute dermal LD_{50} in rats is >5,000 mg/kg. Mancozeb was not significantly toxic to rats after a 4-hour inhalation exposure, with an LD_{50} value of > 5.14 mg/L. Mancozeb is classified as not irritating to skin on initial contact and is a moderate eye irritant. It has been classified as not a sensitizer in the Buehler test.

iii. *ETU*. The mouse acute oral LD_{50} is 4,000 mg/kg/day and the rat acute oral LD_{50} is 545 mg/kg/day. ETU is a moderate to weak sensitizer.

2. *Genotoxicty*. Regarding genotoxicity, maneb and mancozeb have been adequately tested in a wide variety of *in vitro* and *in vivo* mutagenicity tests. Although EPA believes maneb and mancozeb have some genotoxic potential, and the World Health Organization (WHO) has said the evidence for genotoxicity is equivocal, Griffin is informed that the well-conducted scientifically valid studies demonstrate mancozeb is not genotoxic in mammalian systems. Mancozeb is negative in the Ames test and negative *in vitro* and *in vivo* somatic and germ cell tests. It did not induce unscheduled DNA synthesis (UDS). These same conclusions would be expected to apply to maneb. In fact, the FAO and WHO concluded ''that maneb is not genotoxic.''

The WHO reviewed the genotoxicity of ETU in 1993 and concluded that ETU is not genotoxic in mammalian systems. EPA has classified ETU as being weakly genotoxic, at most.

3. *Reproductive and developmental toxicity*. Maneb and mancozeb do not produce birth defects and are not toxic to the developing fetus at doses below those which are toxic to the mother.

i. *Maneb*. The 1993 FAO/WHO Toxicology Evaluations summarized two rat studies as follows: NOAEL - 20 mg/kg/day, LOAEL - 100 mg/kg/day (LOAEL effects being decreased maternal body weight gain and food consumption; embryofetoxicity); NOAEL - 100 mg/kg/day, LOAEL 500

mg/kg/d (LOAEL effects being decreased maternal body weight gain and food consumption, embryofetotoxicity and teratogenicity).

ii. *Mancozeb*. The mancozeb maternal no observable effect level (NOEL) was established at 30-32 mg/kg/day in rats and rabbits. The fetal NOEL is 128 mg/kg/day in rats and > 80 mg/kg/day in rabbits. The parental no observable adverse effect level (NOAEL) was 120 ppm (7.0 mg/kg/day) in a 2-generation reproduction study in rats. Mancozeb had no effect on reproduction, on the microscopic appearance of the reproductive organs, or on neonatal survival or growth below adult toxic levels in appropriate studies.

iii. *ETU*. In a 2-generation rat reproduction study, the ETU parental NOEL was 2.5 ppm, or 0.11-0.43 mg/kg/day, and there were no reproductive effects. The developmental toxicity of ETU has been studied in six species and the results are species-specific. ETU did not produce developmental effects in mice (NOEL-100 mg/kg/day), rabbits (NOEL-40 mg/kg/day), guinea pigs, or cats. In hamsters, the NOEL was 100 mg/kg/day. In rats, the maternal NOEL was 50 mg/kg/day, with a fetal NOEL of 5-15 mg/kg/day.

4. *Chronic toxicity*. The chronic toxicity of the EBDCs is driven by its metabolite ETU. The primary effects are on the pituitary-thyroid-liver axis.

i. *Maneb*. While the EPA Maneb Chemical Fact Sheet does not include chronic toxicology information due to data gaps at the time of publication, combined chronic-oncogenic long-term studies are summarized in the 1993 FAO/WHO Toxicology Evaluations: NOAEL - 20 mg/kg/day, LOAEL - 67 mg/kg/day (LOAEL effects: decreased body weight, T4; increased 131I half-life, thyroid weight).

ii. *Mancozeb*. In a 2-year combined chronic toxicity/oncogenicity study in the rat, the NOEL was 125 ppm (4.8 mg/kg/day) based on thyroid effects. An increased incidence of thyroid tumors was seen at the highest dose of 750 ppm. These effects are likely due to ETU exposure resulting from bioconversion of mancozeb in the rat. This is consistent with the toxicology of ETU, which is described below. In comparison with laboratory animals, humans are expected to exhibit a lesser degree of sensitivity to thyroid inhibitors because humans possess a substantial reserve supply of thyroid hormone, much of it carried in serum bound to thyroxine-binding globulin. This protein is missing in rodents. Additionally, there is a threshold effect for thyroid tumors and the levels of human exposure are well below those that produced tumors in the rat study. The WHO concluded that the data support an RfD for mancozeb of 0.05 mg/kg/day based on this study. An EBDC group ADI of 0.03 mg/kg/day was established by the WHO in 1993.

In an 18-month mancozeb combined chronic toxicity/oncogenicity study in the mouse, the NOEL was 1,000 ppm, or 13 mg/kg/day. No tumors were seen in any dose in this study. In a 1-year dog feeding study, the NOEL was 200 ppm, or 7.8 mg/kg/day.

In a 21-day mancozeb dermal toxicity study in the rat, the NOEL was 1,000 mg/kg/day, with no effects seen at the limit dose. Respiratory administration to rats for 13 weeks decreased body weights and serum T4 levels, and induced thyroid hyperplasia. All effects were reversible after 13 weeks of post-exposure recovery.

iii. *ETU*. In an 18-month mouse feeding study for ETU by the National Toxicology Program (NTP), the NOEL was 100 ppm, or 17 mg/kg/day. Tumors of the liver, thyroid, and pituitary were seen at 330 and 1,000 ppm. A 2-year rat feeding chronic/oncogenicity study established a NOEL of 5 ppm, or 0.37 mg/kg/day. Tumors were seen in the thyroid and pituitary. The WHO established an RfD of 0.004 mg/kg/day based on these data.

5. *Carcinogenicity*. Prolonged ingestion of ETU at very high levels has caused thyroid and pituitary tumors in rats and mice and an increase in liver tumors in mice. Thyroid tumors were also formed when mancozeb was fed to rats at high doses (750 ppm) for long periods of time. It is generally accepted that these tumors result from ETU formation in the rat from feeding high doses of mancozeb. Because 7.5 percent of EBDC is converted to ETU in rats, feeding 750 ppm of EBDC can produce enough ETU to cause tumors in these animals. No carcinogenic effects were seen from feeding maneb and mancozeb to mice.

ETU is classified as a B_2 oncogen with a Q* of 0.06 $(mg/kg/day)^{-1}$. Maneb and mancozeb are also classified as B_2 oncogens because of ETU.

C. Aggregate Exposure

1. *Dietary exposure*. The consumer exposure to EBDC and ETU residues was measured in a market basket survey during an EPA Special Review which concluded in 1992. The data showed that aggregate ETU exposure from all current uses is less than 50% of the RfD. More specifically, Griffin residue data show no detectable residues of ETU on walnuts. Even if low levels of residues were present, mean per capita consumption of walnuts is negligible. USDA dietary consumption data from 1977-78 indicates that it is 0.0048243 g/kg bw/day for the U.S. general population. Moreover, there is no concern with identifiable subpopulations (see infants and children consumption).

FQPA requires EPA to use ''available information'' to consider risks to infants and children before establishing a tolerance. Available information demonstrates that dietary exposures to infants and children from walnuts is immaterial; furthermore, there are also no processed food uses for walnuts.

2. *Drinking water*. Maneb and mancozeb have no tendency to contaminate groundwater or drinking water because they degrade rapidly in soil and water, have low solubility in water, and are absorbed to soil. Although the water solubility of ETU is relatively high, ETU is not expected to contaminate groundwater for several reasons. First, ETU is only present in the soil as the result of degradation of the parent EBDCs (maneb or mancozeb), and it is being degraded at the same time it is being formed. Thus, the ETU concentration will always be low. Second, the degradation of ETU is rapid, thus it will degrade before it can move.

Data from laboratory studies and field dissipation studies have been integrated in computer modeling studies to predict the movement of maneb and mancozeb and ETU in California from EBDC applications on tomatoes and pears (mancozeb only) using the USDA GLEAMS model, which accounts for degradation products as well as the parent. The model predicts that there would be no measurable residues near the bottom of the rooting zone of tomatoes and pears, even with a heavy amount of simulated rainfall. Therefore, the model predicts that maneb, mancozeb and ETU will not leach into groundwater. The modeling predictions are consistent with the fact that EBDCs and ETU degrade rapidly in soil and with the results of actual field dissipation studies.

The most direct evidence that ETU will not contaminate groundwater comes from an extensive review of actual groundwater samples that have been analyzed for ETU. In EPA's own National Pesticide Survey, only one well out of 1,295 samples had an ETU residue. There were no measurable ETU residues in community wells, with a sensitivity of 0.0045 ppm. The one residue was in an area where EBDC fungicides are not heavily used. Analysis of nearly 100 additional samples in state surveys did not show any confirmed residues of ETU, even in

vulnerable areas such as Florida, Maine and New York.

Specific to walnuts which are grown almost exclusively in California, the California Environmental Protection Agency's Pesticide Well Inventory Database reveals extensive annual sampling for maneb and ETU during the period August 15, 1984 to September 29, 1994, but only one ETU detect (10 years ago in 1987) at 0.725 ppb. After not finding ETU for decade, CDPR ceased testing for EBDCs.

Additionally, maneb, mancozeb and ETU degrade rapidly in natural water/sediment systems. Thus, ETU is not likely to be present in drinking water from natural surface water systems.

3. *Non-dietary exposure*. Mancozeb is labeled for application to residential lawns only by commercial applicators, and both maneb and mancozeb are labelled for ornamentals and vegetables by homeowners or professional applicators. Mancozeb products are commonly applied to golf course greens to control a broad complex of turf diseases. Application to golf course fairways is less common. There are no reliable data to assess the exposure from these uses.

Any acute exposures to children would come from oral or dermal exposure. As previously discussed, maneb and mancozeb are not orally or dermally acutely toxic. Furthermore, golf is not played by infants or children; therefore, no exposure to infants and children would be expected. Thus, there is a reasonable certainty that no harm would occur to infants or children from these uses. Regardless, there are no non-occupational exposures associated with walnut uses.

D. Cumulative Effects

The toxicological effects from maneb and mancozeb are due to ETU. Other EBDC fungicides, including metiram and zineb are also converted to ETU. The EBDC fungicides have been extensively reviewed by the US-EPA as part of a Special Review which was concluded in 1992 with publication of the PD4 document. These fungicides were regulated against their common metabolite, ETU, and use restrictions were enacted as part of the conclusion of the Special Review. As a result, common mode of action has received considerable evaluation by the Agency and currently approved risk levels have already accommodated any potential concerns.

E. Safety Determination

1. *U.S. population*. DRES analyses for the U.S. general population show vanishingly small oncogenic risks from combined maneb and ETU residues on walnuts (reflective of mancozeb, as well, since 100% maneb application assumed for calculation). The Combined Oncogenic Risk for Maneb and ETU Residues for the U.S. population 48 states subgroup is 1.7×10^{-9} (ETU Oncogenic Risk). The general U.S. population oncogenic risk with consumption of walnuts is essentially no different than the risk without walnut consumption. An ETU oncogenic risk of 10^{-9} is three orders of magnitude below the FQPA standard, again a negligible contribution.

The RfD of ETU will not be exceeded. In concluding that EBDC Special Review, EPA calculated that the 45 crops on the EBDC labels occupied 47% of the RfD for the general population using a safety factor of 3,000, resulting in an RfD of 0.00008 mg/kg/day (established in 1988). With a new complete database, the WHO established a reference dose of 0.004 mg/kg/day. Because the WHO evaluation used all recently developed data, Griffin believes their number is appropriate. With this RfD and with addition of turnips, mustard greens, and collards to the maneb label since the Special Review ended, the dietary exposure to ETU will utilize less than 2% of the RfD. The incremental RfD utilized for the U.S. general population by walnut uses, a fractional 0.71×10^{-3}, is so minute it does not change this number. The total percent RfD utilized by all uses, including addition of walnuts, is well below the 100% RfD level, and is not perceptibly changed by addition of walnut uses.

The sole acute risk would be for women of childbearing age. In concluding the EBDC special review, EPA calculated that the Margin of Exposure (MOE) for mancozeb would be 4, 985 based on field trial data and concluded the margin would be adequate. The MOE would be even higher based on the consumer exposure data from the market basket survey. Thus, there is adequate safety for this group. Because walnuts have such a low dietary consumption, it will not add to the exposure. Thus, there is a reasonable certainly that no harm will result from EBDC uses generally, and walnut uses specifically.

EPA has previously determined that the dietary risk from ''all EBDC treated crops combined'' is acceptable; this summary of exposure and toxicological safety shows that use of maneb and mancozeb on walnuts will not materially increase that risk. FQPA anticipates that tolerances will be reviewed over the next decade. (See FFDCA sections 408 (b)(2)(E)(ii) and 408(q)). The Agency should issue the walnut time-limited tolerances on maneb and mancozeb now, since this process will provide the opportunity for the Agency to visit any broader questions that may arise in the future as to the tolerances at issue.

2. *Infants and children*. As with the U.S. general population, there is no concern with identifiable subpopulations. The consumption figures for walnuts are: U.S. general population -- 0.0048243 g/kg bw/day; non-nursing infants -- 0.0029131 g/kg bw/day, children 1-6 -- 0.0133432 g/kg bw/day, and children 7-12 --- 0.0087970 g/kg bw/day. Available information demonstrates that exposures to infants and children from walnuts is immaterial. In addition, there are no processed food uses for walnuts. Thus, the raw crop's dietary impact for children is *de minimis*. In fact, the PD4 separate dietary analysis for children and infants that considered far more extensive uses than walnuts found risks no greater than those of the general population, even when overstated by calculations using an unrealistic lifetime exposure. Specifically, EPA calculated the dietary risk to infants and children from the allowed 45 uses to be 3.7×10^{-9} and 2.6×10^{-8}, respectively, adjusted for a revised Q* of 0.06 $(mg/kg/day)^{-1}$. [57 FR 7521 March 2, 1992] With addition of the greens uses, the risks to these subgroups is still less than 1×10^{-7}.

DRES analyses for infants and children show vanishingly small oncogenic risks from combined maneb and ETU residues on walnuts (reflective of mancozeb, as well, since 100% maneb application assumed for calculation). The Combined Oncogenic Risk for Maneb and ETU Residues (ETU Oncogenic Risk) for the subgroups: U.S. population 48 states -- 1.7×10^{-9}; Non-nursing infants < 1 yr (1 yr lifetime corrected) -- 1.4×10^{-11}; Children 1-6 years (6 yr lifetime corrected) -- 4.0×10^{-10}; Children 7-12 years (6 yr lifetime corrected) -- 2.6×10^{-10}. The incremental oncogenic risk for infants and children is well below the 1×10^{-6} FQPA standard of ''reasonable certainty of no harm.'' Non-nursing infants at 10^{-11} are five orders of magnitude below this standard. Even the highest children's group (1-6 years old) at 10^{-10} is an infinitesimal four orders of magnitude lower than the standard.

The Agency also estimated that the 45 crops allowed at the end of the special review occupied less than 50% of the RfD of 0.00008 mg/kg/day for infants and children. With addition of greens and use of the WHO ETU ADI of 0.004

mg/kg/day, ETU utilizes less than 2% of the ADI for infants and children.

The reproductive and developmental toxicity does not require additional safety factors because the database for maneb, mancozeb and ETU is complete. Furthermore, the NTP evaluated the toxicity of the ETU *in utero* in rats and mice and found that there was no significant increase in toxicity, with the exception of a slight increase in rat thyroid tumors, which have a threshold effect. Thus, prenatal and postnatal exposure does not lead to increased sensitivity in infants and children, and there is no evidence that ETU would present only unusual or disproportionate hazard to infants and children. Therefore, there is no need to impose an additional safety factor for infants and children.

FQPA anticipates that tolerances will be reviewed over the next decade. (*See* FFDCA sections 408 (b)(2)(E)(ii) and 408(q)). This process will provide the opportunity for the Agency to visit any broader questions that may arise in the future as to the tolerances at issue.

F. International Tolerances

There is no Codex MRL for walnuts. Codex has established MRLs for the dithiocarbamate group, including maneb and mancozeb, on 21 crops and proposed MRLs on 29 additional substrates.

3. Rohm and Haas Company

PP 2E4141

EPA has received a pesticide petition (PP 2E4141) from Rohm and Haas Company, 100 Independence Mall West, Philadelphia, PA 19106-2399 proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing an import tolerance for residues of the fungicide myclobutanil and free and bound forms of its metabolite in or on the raw agricultural commodity bananas at 4.0 parts per million (ppm) in the whole fruit (0.8 ppm in edible portion). An adequate analytical method is available for enforcement purposes. 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 metabolism*. The metabolism of myclobutanil in plants is well understood. The chemical identities of probable plant residues resulting from the use of myclobutanil on bananas have been elucidated. The major metabolite is alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile. Analyses indicate that the majority of the residue is located on the banana peel.

2. *Analytical method*. Myclobutanil residues, parent plus free and bound alcohol metabolites, are measured at an analytical sensitivity of 0.01 mg/kg in most crops by extraction of samples, partitioning into an organic solvent, clean up on silica gel, and GLC using nitrogen specific thermionic detection. Myclobutanil residues in animal commodities are measured in essentially the same manner with the additional diol metabolite in milk.

3. *Magnitude of residues*. The residue levels found on banana peel ranged between 1.02 and 1.62 ppm at a 200 ppm application rate and between 1.32 and 3.77 ppm at a 400 ppm application rate. In general, the average total residues in the edible pulp were a small percentage (5.8 to 7.8%) of the average total residues in the peel.

B. Toxicological Profile

1. *Acute toxicity*. Myclobutanil is essentially non-toxic after administration by the oral, dermal and respiratory routes. Myclobutanil is not irritating to skin (Draize score = 0), slightly irritating to the eyes (mean irritation score = 0), and it is not a sensitizer. The highest EPA acute toxicity category is III based on ocular irritation. No evidence exists regarding differential sensitivity of children and adults to acute exposure.

2. *Genotoxicity*. A reverse mutation assay (Ames), point mutation in CHO/HGPRT cells, *in vitro* and *in vivo* (mouse) cytogenetic assays, unscheduled DNA synthesis, and a dominant-lethal study in rats were conducted. All were negative for mutagenic effects.

3. *Reproductive and developmental toxicity*. In assessing the potential for additional sensitivity of infants and children to residues of myclobutanil, data were considered from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study 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.

From the rat developmental study, the maternal (systemic) no-observed-effect level (NOEL) was 93.8 mg/kg/day, based on rough hair coat, and salivation at the lowest-observed effect level (LOEL) of 312.6 mg/kg/day. The developmental (pup) NOEL was 93.8 mg/kg/day, based on increased incidences of 14th rudimentary and 7th cervical ribs at the LOEL of 312.6 mg/kg/day. From the rabbit developmental study, the maternal (systemic) NOEL was 60 mg/kg/day, based on reduced weight gain, clinical signs of toxicity and abortions at the LOEL of 200 mg/kg/day. The developmental (pup) NOEL was 60 mg/kg/day, based on increases in number of resorptions, decreases in litter size, and a decrease in the viability index at the lowest effect level (LEL) of 200 mg/kg/day.

From the rat reproduction study, the maternal (systemic) NOEL was 2.5 mg/kg/day, based on increased liver weights and liver cell hypertrophy at the LOEL of 10 mg/kg/day. The developmental (pup) NOEL was 10 mg/kg/day, based on decreased pup body weight during lactation at the LEL of 50 mg/kg/day. The reproductive (parental) NOEL was 10 mg/kg/day, based on increased incidence of stillborns, and atrophy of the testes, epididymides, and prostate at the LEL of 50 mg/kg/day.

4. *Chronic toxicity*. In 2-year combined chronic toxicity/oncogenicity studies in rats and 18-month oncogenicity studies in mice, the overall NOEL was 80 ppm (2.49 mg/kg/day) based on decreased body weight, and liver and testicular atrophy. In a 1-year chronic toxicity study in dogs, the NOEL was 3.83 mg/kg/day based on hepatotoxicity. The LOEL was 14.3 mg/kg/day. The Reference Dose (RfD) of 0.025 mg/kg/day was established by the Agency based on the chronic feeding study in rats with a NOEL of 2.5 mg/kg/day and an uncertainty factor of 100. There was testicular atrophy at the lowest effect level (LEL) of 9.9 mg/kg/

Twenty four-month rat and 18-month mouse chronic feeding/carcinogenicity studies with myclobutanil produced no statistically significant increase in the incidence of combined, benign or malignant tumors. Worst-case estimates of dietary intake of myclobutanil in human adults and children indicate effects on the liver will not occur, thus there is a reasonable certainty of no harm. Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986, EPA has classified myclobutanil as a Group E chemical (no evidence of carcinogenicity for humans) based on the results of carcinogenicity

studies in two species. The doses tested were adequate for identifying a cancer risk.

5. *Animal metabolism*. The metabolism of myclobutanil in animals is adequately understood for the purposes of this tolerance.

C. Aggregate Exposure

1. *Dietary exposure*. Established U.S. tolerances for myclobutanil and its metabolites are found in 40 CFR 180.443, and range from 0.02 ppm for cotton seed and eggs to 5.0 ppm for cherries (sweet and sour). There are no livestock feed items associated with the proposed use on bananas, so no additional livestock dietary burden will result from this registration. Therefore, existing meat, milk and poultry tolerances are adequate.

For the purposes of assessing the potential dietary exposure under this petition, the estimated aggregate exposure was based on the theoretical maximum residue contribution (TMRC) from the tolerances for myclobutanil on all registered uses plus banana pulp, the edible portion of whole bananas, at 0.8 ppm. The tolerance for myclobutanil on bananas (whole fruit) is 4.0 ppm. The TMRC is obtained by multiplying the tolerance level residues for banana pulp by the consumption data which estimates the amount of bananas and other products eaten by various population subgroups.

The RfD based on the 2-year rat chronic feeding study (NOEL of 2.49 mg/kg bwt/day) and using a hundred-fold uncertainty factor is calculated to be 0.025 mg/kg bwt/day. The TMRC from previously established tolerances and tolerances established here is 0.003286 mg/kg bwt/day for the general population and utilizes 13.1% of the RfD. The percentage of the RfD for the most highly exposed subgroup, non-nursing infants (less than 1 year old) is 72.3%. The TMRC was calculated based on the assumption that myclobutanil occurs at the maximum legal limit in all of the dietary commodities for which tolerances are proposed. Even with this probable large overestimate of exposure/risk, the TMRC is well below the RfD for the population as a whole and for each of the 22 subgroups considered.

Thus, the dietary risk from exposure to myclobutanil appears to be minimal for the use on bananas. In conducting this exposure assessment, very conservative assumptions (100% of bananas will contain myclobutanil residues and those residues would be at the level of the tolerance) were made which results in an overestimate of human exposure. Thus, in making a safety determination for these tolerances, this conservative exposure assessment is taken into account.

2. *Drinking water*. Myclobutanil will not contaminate groundwater or drinking water because of its adsorptive properties on soil, solubility in water, and degradation rate. Data from laboratory studies and field dissipation studies have been used in the USDA PRZM/GLEAMS computer model to predict the movement of myclobutanil. The model predicts that myclobutanil will not leach into groundwater, even if heavy rainfall is simulated. The modeling predictions are consistent with the data from environmental studies in the laboratory and the results of actual field dissipation studies. There are no data on passage of myclobutanil through water treatment facilities and there are no State water monitoring programs which target myclobutanil.

Based on the available studies used in the assessment of environmental risk, it is not anticipated that there will be exposure to residues of myclobutanil in drinking water. Review of terrestrial field dissipation data indicated that myclobutanil did not leach into groundwater in either sandy loam or coastal soil. There is no established Maximum Concentration Level for residues of myclobutanil in drinking water. No drinking water health advisories have been issued for myclobutanil. The ''Pesticides in Groundwater Database'' has no information concerning myclobutanil. Based on the available data, the Agency does not anticipate that there will be significant exposure to the general population from myclobutanil residues in drinking water. Since myclobutanil is unlikely to leach into groundwater, there is no increased risk from this source.

3. *Non-dietary exposure*. EPA has not provided Rohm and Haas Company with an estimate of non-occupational exposure for myclobutanil, however, there are no products registered in the United States for home-owner use which contain myclobutanil. While this does not preclude potential exposure, the market channels for home-owner products do not contain myclobutanil. This makes the potential for non-occupational exposure to the general population essentially nil and the contribution from this source is not expected to be significant.

D. Cumulative Effects

EPA is aware of and has considered the potential for cumulative effects of myclobutanil and other substances that have a common mechanism of fungicidal activity. These are commonly designated as the DMI fungicides. The Rohm and Haas Company, other producers, University advisors, economic consultants, and the EPA are well aware of the existing national IPM and resistance management programs for these fungicides which strongly discourage the use of multiple products either concomitantly or in succession within the same season. The activities within these highly publicized programs and the Fungicide Resistance Action Committee, which monitors fungal resistance on an annual basis, support the conclusion that overlapping use of DMI fungicides on the same crop are unlikely. In addition, Rohm and Haas Company is not aware of any toxicological data available to EPA or to the producers which suggest that there is a common mechanism of mammalian or ecological toxicity among these fungicidal products. Therefore, it is reasonable to conclude that EPA has reliable information to indicate that toxic effects produced by myclobutanil should not be considered to be cumulative with those of any other chemical compounds. Thus, consideration of a common mechanism of toxicity for these fungicidal products is not appropriate at this time. EPA should consider only the potential risks of myclobutanil in its aggregate exposure assessment.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions described above, based on the completeness and reliability of the toxicity data, it was concluded that aggregate exposure to myclobutanil will utilize 13.1% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. It is therefore concluded that there is a reasonable certainty that no harm will result from aggregate exposure to myclobutanil residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of myclobutanil, data were considered from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study 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.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database relative to pre- and post-natal effects for children is complete. Further, for the chemical myclobutanil, the NOEL at 2.5 mg/kg/day from the rat study, which was used to calculate the RfD, is already lower than the NOELs from the developmental studies in rats and rabbits by a factor of approximately 4-fold.

The effects observed in the reproductive toxicity study suggest that there is no unique sensitivity for infants and children. Therefore, the data support a conclusion that an additional uncertainty factor is not warranted and that the RfD at 0.025 mg/kg/day is appropriate for assessing aggregate risk to infants and children.

Using the conservative exposure assumptions described above, it was concluded that the percent of the RfD that will be utilized by aggregate exposure to residues of myclobutanil ranges from 13.1% for adults up to 72.3% for non-nursing infants. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, EPA has already published a conclusion which indicates that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to myclobutanil residues.

F. International Tolerances

There are Codex maximum residue levels (MRL) established for residues of myclobutanil for apricot, cherry, peach, plum/prune (fresh), prune (dried), grapes, apples, and pears. Rohm and Haas company has proposed modifications to the current CXL for stone fruits only to accommodate US GAP.

[FR Doc. 97–20216 Filed 7-31-97; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission for Extension Under Delegated Authority, 5 CFR 1320 Authority; Comments Requested

July 28, 1997.

SUMMARY: The Federal Communications Commission, 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(s), as required by the Paperwork Reduction Act of 1995, Pub. L. 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: Persons wishing to comment on this information collection should submit comments by September 30, 1997.

ADDRESSES: Direct all comments to Judy Boley, Federal Communications Commission, Room 234, 1919 M St., NW., Washington, DC 20554 or via internet to jboley@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Judy Boley at 202–418–0214 or via internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Approval No.: 3060–0132.

Title: Supplemental Information—72–76 MHz Operational Fixed Stations.

Form Number: FCC Form 1068–A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or households; Business or other for-profit; Not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents: 300.

Estimate Hour Per Response: .50 hours.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 150 hours.

Needs and Uses: FCC Rules require that the applicant agrees to eliminate any harmful interference caused by the operation to TV reception on either channel 4 or 5 that might develop. This form is required by the Communications Act of 1934, as amended; International Treaties and FCC Rules, 47 CFR Part 90.257.

FCC staff will use the data to determine if the information submitted will meet the FCC rule requirements for the assignment of frequencies in the 72–76 MHz band.

OMB Approval No.: 3060–0021.

Title: Civil Air Patrol Radio Station License.

Form Number: FCC Form 480.

Type of Review: Extension of a currently approved collection.

Respondents: Not-for-profit institutions.

Number of Respondents: 12.

Estimate Hour Per Response: .84 hours.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 1 hour.

Needs and Uses: FCC Rules require that applicants file the FCC Form 480 to apply for a new, renewed, or modified Civil Air Patrol Radio Station License. This form is required by the Communications Act of 1934, as amended; International Treaties and FCC Rules, 47 CFR Parts 1.922, 87.21, and 87.31.

The data will be used by Commission personnel to evaluate the application to issue licenses, to provide information for enforcement and rulemaking proceedings and to maintain a current inventory of licensees.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 97–20257 Filed 7–31–97; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 2212]

Petitions for Reconsideration and Clarification of Action in Rulemaking Proceedings

July 29, 1997.

Petitions for reconsideration have been filed in the Commission's rulemaking proceeding listed in this