Management Plan, Implementation, Mogollen Rim, Coconino National Forest, Coconino County, AZ, Due: September 29, 1997, Contact: John Gerritsma (520) 354–2216.

EIS No. 970333, Final EIS, AFS, ID, Fourmile Timber Sale, Timber Harvesting and Road Construction, Payette National Forest, New Meadow Ranger District, Adam County, ID, Due: September 29, 1997, Contact: Debbie Ellis (218) 347–0300.

Dated: August 26, 1997.

B. Katherine Biggs,

Associate Director, Office of Federal Activities.

[FR Doc. 97–23119 Filed 8–28–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–5483–9]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared August 4, 1997 Through August 8, 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–FHW–K40142–CA Rating EC2, CA–4 ''GAP'' Closure Project, Improvements between I–80 and Cunninings Skyway, Funding, NPDES Permit and COE Section 404 Permit, City of Hercules, Contra Costa County, CA.

Summary: EPA expressed environmental concerns due to: a need for additional information regarding wetlands, water and biological resources and air quality data and analysis.

ERP No. D–FHW–K40224–CA Rating EU3, I–880/CA–92 Interchange Reconstruction, I–880 from Winton Avenue to Tennyson Road and CA–92 from Hesperian Boulevard to Santa Clara Street, Funding, City of Hayward, Alameda County, CA.

Summary: EPA found the DEIS for the I–880/92 interchange project to have inadequate information because the DEIS did not account for the related SR 92 San Mateo-Hayward bridge widening project which had been analyzed in a separate document. EPA believes the two projects should be analyzed together as one since both are dependent on one another, and that the information did not present a complete picture of the impacts to the public and to the decisionmaker.

ERP No. D–FHW–K40225–CA Rating EC2, Marin US–101 High Occupancy Vehicle (HOV) Gap Closure Project, Construction from US 101 I–580 on US–101 from Lucky Drive to North San Pedro Road and I–580 from Irene Street to US–101, Funding, COE Section 404 and Bridge Permits, Marin County, CA.

Summary: EPA expressed environmental concerns regarding potential air quality impacts, relocation of the San Rafael Viaduct, impacts to the future rail project, minimization of impacts of coastal zone resources, and indirect impacts.

ERP No. D–TVA–E09803–MS Rating EC2, Exercise of Option Purchase Agreement with LSP Energy Limited Partnership for Supply of Electric Energy, Construction and Operation, Batesville Generation Facility, Funding, COE Section 10 and 404 Permits and NPDES Permit, City of Batesville, Coahoma, Panola, Quitman and Yalobusha Counties, MS.

Summary: EPA's primary concern involves the fact that the proposed power plant site is not close to waterbodies required for process water supply and discharge, so that pipeline interconnection with associated impacts (including loss of forested wetlands) are proposed.

Final EISs

ERP No. F–FHW–J40140–MT, US 93 Highway Transportation Improvements, between Hamilton (Milepost 49.0) to Lolo (Milepost 83.2), Funding and COE Section 404 Permit, Ravalli and Missoula Counties, MT.

Summary: EPA expressed environmental concerns regarding potential induced and hastened changes in the pattern of land use, population density or growth rate of the Bitteroot Valley resulting indirectly from the project and potential adverse effects to wetlands, riparian areas, wildlife habitat, and other natural systems, including ecosystems.

Dated: August 26, 1997.

B. Katherine Biggs,

Associate Director, Office of Federal Activities.

[FR Doc. 97–23120 Filed 8–28–97; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[PF–758; FRL–5738–2]

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–758, must be received on or before September 29, 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: The contact person listed in the table below:

Contact Person	Office location/telephone number	Address
Beth Edwards, ...	Rm. 211, CM #2, 703–305–5400, e-mail:edwards.beth@epamail.epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA
Amelia Acierto	4th floor, CS1, 703–308–8377, e-mail: acierto.amelia@epamail.epa.gov.	2800 Crystal Drive, Arlington, VA.
Bipin Gandhi, ...	Rm.4W53, CS1, 703–308–8380, e-mail: gandhi.bipin@epamail.epa.gov.	Do.

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–758] (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–758] 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: August 20, 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. American Cyanamid Company

PP 3E4246

EPA has received a pesticide petition (PP 3E4246) from American Cyanamid Company, Agricultural Products Research Division, P.O. Box 400, Princeton, NJ 08543-0400, 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 to establish an exemption from the requirement of a tolerance for residues of Polyvinyl Chloride (PVC) when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest, under 40 CFR 180.1001(c). 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. Toxicity Data

As part of the EPA policy statement on inert ingredients published in the **Federal Register** of April 22, 1987 (52 FR 13305), the Agency set forth a list of studies which would generally be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. However, where it can be determined without the data that the inert ingredient will present minimal or no risk, the Agency generally does not require some or all of the listed studies to rule on the proposed tolerance or exemption from the requirement of a tolerance for an inert ingredient. Cyanamid believes that the data and information described below is adequate to ascertain the toxicology and characterize the risk associated with the use of PVC as an inert ingredient in pesticide formulations applied to growing crops and raw agricultural commodities after harvest.

In the case of certain chemical substances that are defined as ''polymers'', the EPA has established a set of criteria which identify categories of polymers that present low risk. These criteria (described in 40 CFR 723.250) identify polymers that are relatively unreactive and stable compared to other chemical substances as well as polymers that typically are not readily absorbed. These properties generally limit a polymer's ability to cause adverse effects. In addition, these criteria exclude polymers about which little is known. The EPA believes that polymers meeting the criteria noted below will present minimal or no risk.

Polyvinyl chloride (PVC) conforms to the definition of polymer given in 40 CFR 723.250(b) and meets the following criteria that are used to identify low risk polymers:

1. PVC is not a cationic polymer, nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

2. PVC contains as an integral part of its composition the atomic elements carbon, chlorine, and hydrogen.

3. PVC does not contain as an integral part of its composition, except as impurities, any elements other than those listed in 40 CFR 723.250 (d)(2)(ii).

4. PVC is not designed, nor is it reasonably anticipated to substantially degrade, decompose, or depolymerize.

5. PVC is not manufactured or imported from monomers and/or other reactants that are not already included on the Toxic Substance Control Act (TSCA) Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. PVC is not a water absorbing polymer.

7. PVC does not contain any group as reactive functional groups.

8. The minimum number-average molecular weight of PVC is listed as 29,000 daltons. Substances with molecular weights greater than 400 generally are not absorbed through the intact skin, and substances with molecular weights greater than 1,000 generally are not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response.

9. PVC has a minimum number-average molecular weight of 29,000 and contains less than 2 percent oligomeric material below molecular weight 500 and less than 5 percent oligomeric material below 1,000 molecular weight.

In addition, PVC is approved by the Food and Drug Administration (FDA) under 21 CFR for contact with food as a component in adhesives (21 CFR 175.105), coatings (21 CFR 175.320), and paper and paperboard (21 CFR 176.180). PVC is also approved by FDA as an indirect food additive used as a basic component of acrylic (21 CFR 177.1010) and cellophane (21 CFR 177.1200) polymers.

PVC is also cleared for use as water pipe for potable water as per FFDCA 201(s).

B. Aggregate Exposure

PVC was one of the earliest and still most widely used plastics. The polymer is ubiquitous in our every day environment as it is commonly used in building materials, furniture, and textiles. It is also cleared by FDA as an indirect food additive due to its use in food packaging materials.

Although exposure to PVC may occur through dietary (e.g., PVC-containing food wrapping), non-occupational (e.g., contact with PVC furniture), and drinking water (e.g., potable water piping, water bottles, etc.) sources, the chemical characteristics of PVC lead to the conclusion that there is a reasonable certainty of no harm from aggregate exposure to the polymer. Given the existing widespread use of PVC, any additional exposure resulting from the approval of the use of PVC as an inert ingredient in pesticide formulations for use on growing crops or to raw agricultural commodities after harvest would be trivial.

C. Cumulative Effects

At this time there is no information to indicate that any toxic effects produced by PVC would be cumulative with those of any other chemical. Given the compound's categorization as a ''low risk polymer'' (40 CFR 723.250) and its proposed used as an inert ingredient in pesticide formulations, there is no reasonable expectation of increased risk due to cumulative exposure to PVC.

D. International Tolerances

Cyanamid is petitioning that PVC be exempt from the requirement of a tolerance based upon its status as a low risk polymer as per 40 CFR 723.250. Therefore, an analytical method to determine residues of PVC in raw agricultural commodities treated with pesticide formulations containing PVC has not been proposed.

There are no Codex maximum residue levels (MRLs) established for PVC.

Residues of PVC are currently exempt from the requirement of a tolerance under 40 CFR 180.1001(e) for use in pesticide formulations applied to animals. (Bipin Gandhi)

2. Merck Research Laboratories, Inc. (Merck)

PP 7F4845

EPA has received a pesticide petition (PP 7F4845) from Merck Research Laboratories, Inc. (Merck), P.O. Box 450, Hillsborough Road, Three Bridges, NJ 08887–0450, 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 tolerances for residues of emamectin benzoate and certain of its degradates in or on the fruiting vegetables crop group (except cucurbits), which includes the raw agricultural commodities eggplants, groundcherries, pepinos, peppers (bell, chili, cooking, and sweet), tomatillos, and tomatoes. Emamectin benzoate is a new insecticide designed for use against the larvae of various Lepidoptera species when applied in the form of an emulsifaiable concentrate formulation (PROCLAIM® 0.16 EC Insecticide) or a soluble granular formulation (PROCLAIM® 5% SG Insecticide).

Merck Research Laboratories, Inc. (Merck) previously has applied for the registration under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of three products containing emamectin benzoate: emamectin benzoate technical (EPA File Symbol 618-RNI); PROCLAIM 0.16 EC Insecticide (EPA File Symbol 618-RNT); and PROCLAIM 5% SG Insecticide (EPA File Symbol 618-RNA). Notice of filing of these applications was published in the **Federal Register** on July 10, 1996 (61 FR 36372). In the previous petition, Merck proposed that the end-use products be registered for use on broccoli, Brussels sprouts, cabbage, cauliflower, celery, and head lettuce. Merck has also submitted a petition under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) for the establishment of permanent tolerances for residues of emamectin benzoate on the raw agricultural commodities (RACs) broccoli, Brussels sprouts, cabbage, cauliflower, celery, and head lettuce. EPA has assigned this petition the number PP 6F4628.

Merck is now submitting this new petition for the issuance of a tolerance for residues of emamectin on the ''fruiting vegetables (except cucurbits)'' crop group, which includes eggplants, groundcherriees, pepinos, peppers (bell, chili, cooking, and sweet), tomatillos, and tomatoes.

The tolerances sought are for the total toxic residue, consisting of the parent insecticide (emamectin benzoate) and four other components that are plant metabolites or photodegradation products. For each RAC the proposed tolerance level is 0.02 ppm. The pesticide chemical that produces such residues is the parent insecticide emamectin benzoate. Further information on the chemical identity and composition of these compounds is set forth in the EPA files for the three applications discussed in the previous paragraph above.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of emamectin benzoate in plants has been studied in lettuce, cabbage, and sweet corn. The major portion of the residue is parent compound and its delta 8,9- photoisomer. Studies of the metabolism of emamectin in animals are not required because the commodities that are the subject of the petition are not significant animal feed items.

2. *Analytical method*. Adequate analytical methods (HPLC-fluorescence methods) are available for enforcement purposes.

3. *Magnitude of residues*. Twenty-three field trials have been conducted: 11 on peppers and 12 on tomatoes. A processing study was also carried out with tomatoes. These trials were conducted in the major U.S. growing areas for these crops.

All trials were conducted under maximum proposed use rates and conditions. Raw agricultural commodity (RAC) samples from all trials were collected a few hours after the last treatment (day 0) and on days 3, 7, and 14. In one trial samples were also collected for use in a processing study.

In day 7 (and later) whole tomato samples, the highest level of the B1a component and of the n-formyl component were each NQ (not quantifiable, less than 5 ng/g); for the

other two components the residues were less than 1 ng/g. In day 7 (and later) pepper samples, the highest B1a residue was 5 ng/g , the highest n-formyl residue was NQ (less than 5 ng/g), and the other two components were less than 1 ng/g in each sample. Thus, the maximum combined residue was less than 12 ng/g (less than 0.012 ppm) in each case. The processing study showed that the residues did not concentrate in tomato puree or paste.

These data support the proposed tolerance of 0.02 ppm for total toxic residues of emamectin benzoate on tomatoes, tomato puree, tomato paste, or peppers, and by extension to remaining members of the fruiting vegetables (except cucurbits) group.

B. Toxicological Profile

The primary toxic effect seen in animal studies of emamectin benzoate is neurotoxicity. No-observed-effect-levels (NOELs) for this effect have been well characterized in multiple studies. Emamectin benzoate has not been shown to be oncogenic or teratogenic in animal studies, it lacks mutagenic activity, and it is not selectively developmentally toxic. The petition refers to toxicity data that establish the following information about the toxicity of emamectin benzoate:

1. *Acute toxicity*. Acute oral LD_{50}: rat, 76–89 mg/kg; CD-1 mouse 107–120 mg/kg; CF-1 mouse, 22–31 mg/kg. *Acute oral neurotoxicity*: rat, NOEL = 5 mg/kg, LOEL = 10 mg/kg. *Acute dermal* LD_{50}: rat and rabbit, >2,000 mg/kg. *Dermal irritation*: rabbit, not irritating to skin. *Eye irritation*: rabbit, severe eye irritant. *Acute inhalation 4-hour* LC_{50}: rat, 2.12–4.44 mg/l.

2. *Mutagenicity*. Emamectin benzoate was tested in a battery of *in vitro* and *in vivo* mutagenicity assays and showed no evidence of mutagenic potential. The photodegradates have also been tested in the Ames bacterial mutagenicity assay and show no mutagenic potential in this test system.

3. *Reproductive and developmental toxicity*. Developmental toxicity: rat, maternal NOEL = 2 mg/kg/day, developmental NOEL = 4 mg/kg/day, developmental LOEL = maternally toxic 8 mg/kg/day (HDT) for developmental delay; rabbit, maternal NOEL = 3 mg/kg/day, developmental NOEL = 6 mg/kg/day (maternally toxic HDT). Developmental neurotoxicity: rat, maternal NOEL = 3.6/2.5 mg/kg/day (HDT), developmental NOEL = 0.6 mg/kg/day, developmental LOEL = 3.6/2.5 mg/kg/day for signs of neurotoxicity in pups. 2-generation reproductive toxicity: rat, parental and reproductive NOEL = 0.6 mg/kg/day, parental LOEL = 3.6/1.8 mg/kg/day (for decreased weight gain and neuronal lesions); reproductive toxicity LOEL = 3.6/1.8 mg/kg/day (for decreased fecundity and signs of neurotoxicity in pups).

4. *Subchronic and chronic toxicity and oncogenicity*. With the single exception of the chronic rat study, LOELs for the following studies are based on clinical signs and/or histopathological evidence of neurotoxicity (described further below). Subchronic (90-day) toxicity: rat, NOEL = 0.5 mg/kg/day, LOEL = 2.5 mg/kg/day; CD-1 mouse, NOEL = 5.4 mg/kg/day (TWA), LOEL = 0.5 mg/kg/day; dog, NOEL = 0.25 mg/kg/day, LOEL = 0.5 mg/kg/day Subchronic (90-day) neurotoxicity; rat, NOEL = 1 mg/kg/day, LOEL = 5 mg/kg/day. Chronic (105-week) toxicity/oncogenicity, rat: NOEL = 0.25 mg/kg/day, LOEL = 1 mg/kg/day (based on decreased body weight and clinical chemistry changes), neurotoxicity NOEL = 1 mg/kg/day, not oncogenic. Chronic (79-week) toxicity/oncogenicity, CD-1 mouse: NOEL = 2.5 mg/kg/day, LOEL = 5 mg/kg (males), 7.5 mg/kg/day (females), not oncogenic. Chronic (53-week) toxicity, dog: NOEL = 0.25 mg/kg/day, LOEL= 0.5 mg/kg./day.

Exposure to sufficiently high doses of emamectin benzoate may be associated with clinical signs of central nervous system (CNS) toxicity and microscopic evidence of CNS/peripheral nervous system (PNS) damage. Neurotoxicity has generally been the most sensitive endpoint for toxicity in oral animal studies with emamectin benzoate. Clinical signs of CNS toxicity resulting from emamectin benzoate exposure include tremors, mydriasis, and changes in motor activity (e.g., lethargy, hyperactivity, and/or ataxia). Nervous system lesions (generally focal and of a low degree of severity) have been observed microscopically in white and gray matter in the brain stem, spinal cord, and peripheral nerves. Sporadic lesions of the optic nerve and/or retina have also been seen at higher dose levels. NOELs have been determined in all studies. The lowest toxic dose level of emamectin benzoate for CNS/PNS lesions (0.5 mg/kg/day) was identified in a 1–year study in dogs (NOEL of 0.25 mg/kg/day).

The CF-l mouse is uniquely sensitive to emamectin benzoate-induced neurotoxicity. Studies have shown that a significant fraction of the members of this strain inherit an inability to produce a P-glycoprotein- one that most strains and species do produce- that functions to resist the entrance of avermectin-type compounds into the central nervous system. P-glycoprotein is also present in the gut of most species and limits absorption of avermectin-type compounds following oral exposure. In a 16–day feeding study in the CF-1 mouse, tremors were seen at 0.3 mg/kg/day of emamectin benzoate with a NOEL of 0.1 mg/kg/day. No histopathologic evidence of neurotoxicity was seen in this study up to the highest dose tested (0.9 mg/kg/day).

Emamectin benzoate photodegrades on plants and in soil. The major photodegradates that are not animal metabolites were tested in a 15-day neurotoxicity study in CF-1 mice. Only one photodegradate showed neurotoxicity (Merck research number L-660,599, the N-formyl-N-methyl degradate). Its NOEL was found to be 0.075 mg/kg/day, slightly lower than the value for the parent compound in the same kind of study, and both clinical signs and peripheral nerve lesions were observed at levels of 0.1 mg/kg/day and higher.

5. *Endpoint selection*. Merck is proposing that the 0.075 mg/kg/day NOEL from the CF-1 mouse 15–day neurotoxicity study with the L–660,599 photodegradate be used as the basis for acute dietary risk assessment. For evaluation of chronic dietary risks, Merck is proposing that the 1-year dog chronic study NOEL of 0.25 mg/kg/day be used. The dog appears to be the most sensitive species to long-term exposure to emamectin benzoate. Accordingly, chronic exposure is compared against a RfD of 0.0025 mg/kg/day, based on the dog study results and an uncertainty factor of 100.

C. Aggregate Exposure

1. *Dietary exposure*. Except for a temporary tolerance associated with an experimental use permit, no tolerances for residues of emamectin benzoate have been established. Merck projects that by the year 2,001, emamectin benzoate will be used on approximately 17% of the acreage for the cole, leafy non-cole vegetable, and fruiting vegetable crops. Chronic dietary exposure analyses were conducted for the overall U.S. population and 26 population subgroups. Assuming 100% of the crops are treated, chronic exposure for the overall U.S. population was estimated to be 0.000005 mg/kg BW/day, and for the most highly exposed subgroup, children 1 to 6 years of age, 0.000007 mg/kg BW/day.

2. *Non-dietary exposure*. No products containing emamectin benzoate have yet been registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for any food or nonfood use. No significant nondietary,

nonoccupational exposure is anticipated.

3. *Drinking water*. The environmental fate of emamectin has been evaluated, and the compound is not expected to contaminate groundwater or surface water to any measurable extent.

D. Cumulative Effects

Emamectin is a member of the avermectin family of natural and synthetic compounds that includes the Merck products abamectin (a naturally occurring compound that is the active ingredient of several insecticides registered under FIFRA) and ivermectin (a human and animal drug made from abamectin). Emamectin is made from abamectin but is less similar to abamectin than is ivermectin. Other companies produce certain other drugs that are members of the avermectin family. Some of the effects seen in toxicity studies of abamectin and ivermectin are similar to some of the effects seen in toxicity studies of emamectin. See the discussion of abamectin and ivermectin in 61 FR 65043 (December 10, 1996). Merck is not aware of any information indicating what, if any, cumulative effect would result from exposure to two or more of these compounds.

E. Safety Determination

1. *U.S. population*— i. *Chronic risk*. Chronic exposures were analyzed with reference to the chronic effects RfD NOEL of 0.0025 mg/kg/day. Assuming 100% of the crops are treated, the chronic exposure estimate was 0.2% of the RfD for the overall U.S. population, and 0.3% of the RfD for the most highly exposed subgroup, children 1 to 6 years of age. If 25% crop treatment is assumed, exposure estimates were less than 0.1% of the RfD for all population groups.

ii. *Acute risk*. Acute exposure analyses were conducted for the overall U.S. population, and the population subgroups (1) women 13 years and older, (2) infants, and (3) children. In addition, Tier 2 and Tier 3 acute analyses were conducted assessing acute exposures against the 0.075 mg/kg/day NOEL. These analyses showed that the margins of exposure (MOEs) calculated from the proposed uses of emamectin benzoate are acceptable whether using a highly conservative approach (Tier 2) or a more realistic (Tier 3) methodology. In the Tier 2 analysis, MOEs were well over 1,000 up to the 95th percentile of exposure for all population groups. In the Tier 3 analysis and assuming 100% of the crops are treated, MOEs up to the 99.5th percentile of exposure were greater than 1,000. Assuming 25% of the crop treated, MOEs were greater than 1,000 up to the 99.9th percentile of exposure. Results of both the chronic and acute dietary exposure analyses clearly demonstrate a reasonable certainty that no harm will result from the proposed uses of emamectin benzoate.

2. *Infants and children*. It is Merck's position that the administration of emamectin benzoate has not been shown to cause developmental or reproductive effects at dose levels below those that are maternally toxic. Even if it were decided to use the 0.6 mg/kg NOEL from the rat developmental neurotoxicity study as an endpoint from which to calculate an RfD, the resulting RfD would not yield a different regulatory outcome unless a very high additional uncertainty factor were also employed. Use of such an extra uncertainty factor is not justified for several reasons. Emamectin benzoate is not a teratogen. In developmental toxicity testing, the compound caused no developmental effects in rabbits; in rats, it caused no malformations, and caused skeletal effects typical of developmental delay only at severely maternally toxic doses. Likewise, no reproductive toxicity or toxicity to pups was seen in the 2-generation reproductive toxicity study except at parentally toxic doses. In the developmental neurotoxicity study, tremors, hind-leg splay, and behavioral effects were seen in pups at a dose level (3.6/2.5 mg/kg/day) at which no maternal clinical signs were noted. However, the dams in the study were discarded after the lactation period without gross necropsy or microscopic examination. In studies in which rats dosed at similar levels were examined microscopically, effects (central and peripheral neural lesions) were seen.

The clinical signs of avermectin-family neurotoxicity seen in neonatal rats are unlikely to be useful predictors of human risk. Young rats are considerably more sensitive to avermectin-type compounds than either adult rats or humans and other primates. (In neonatal rats, unlike humans, the P-glycoprotein levels are only a small fraction of the levels seen in adult rats.) Moreover, data from clinical experience with ivermectin, a related human drug, and studies on ivermectin and abamectin, a related pesticide, demonstrate that both the neonatal rat and the CF–1 mouse overpredict the toxicity of the avermectin-type compounds to humans and to non-human primates.

F. International Tolerances

No Codex maximum residue levels (MRLs) have been established for residues of emamectin benzoate. (Beth Edwards)

3. Milliken & Company

PP 5E4597

EPA has received a pesticide petition (PP 5E4597) from Milliken & Company, M–400, P.O Box 1927, Spartanburg, SC 29304–1927, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR 180.1001(c) to establish an exemption from the requirement of a tolerance for Poly(ethylene glycol) modified FD&C Blue No. 1, Methyl-Poly(ethylene glycol) modified FD&C Blue No. 1; Poly(ethylene glycol) modified Methyl Violet 2B; when used as inert ingredients at the rate not to exceed 0.6 parts per billion (ppb) to impart color to pesticidally-treated seeds. 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*. No specific residue studies have been conducted on the colorants in raw agricultural commodities or in processed foods. However, the aggregate exposure estimates, discussed above, are based on the assumption that an exaggerative level of PEG-modified FD&C Blue No. 1, Methyl-PEG-modified FD&C Blue No. 1, and PEG-modified Methyl Violet 2B applied to seeds will be absorbed by growing plants and enter the diet. Even based on this exaggerative assumption, the maximum potential dietary exposure to the colorants is minuscule.

2. *Analytical method*. Section 408(c)(3)(B) provides for circumstances where no need exists for a practical method for detecting and measuring levels of pesticide residue in or on food. In this instance, because the colorants of interest are inert ingredients and since the exemption from the requirement of a tolerance has no numerical limitation, analytical methods are not required for enforcement purposes for these colorants.

B. Toxicological Profile

1. *Acute toxicity*. The results of acute oral toxicity studies indicate that PEG-modified FD&C Blue No. 1 has very low

toxicity by the oral route. Specifically, PEG-modified FD&C Blue No. 1 has an acute oral LD_{50} of greater than 5,000 milligrams per kilogram in rats. An additional test material having slightly smaller side chain lengths than PEG-modified FD&C Blue No. 1 also showed an acute oral LD_{50} of greater than 5,000 milligrams per kilogram in rats. PEG-modified FD&C Blue No. 1 is closely related to FD&C Blue No. 1; however, the PEG-modified FD&C Blue No. 1 is of a higher molecular weight than FD&C No. 1. FD&C Blue No. 1, itself, is exempt from the requirement of a tolerance under 40 CFR 180.1001 and also is cleared by the Food and Drug Administration for use in coloring food and for coloring drugs under 21 CFR 74.101 and 74.1101, respectively. The acute oral LD_{50} for FD&C Blue No. 1 has been determined to be greater than 2,000 mg/kg in rats (Lu and Lavallee, 1964). Thus, the acute toxicity data submitted in support of this petition support the conclusion that PEG-modified FD&C Blue No. 1 is of a lower order of toxicity than FD&C Blue No. 1, itself. Such a result could be expected since, in general, compounds of higher molecular weights are more poorly absorbed and consequently are typically less toxic than closely related lower molecular weight materials.

Along the same lines, it should be noted that Methyl-PEG-modified FD&C Blue No. 1, is another material that is closely related to FD&C Blue No. 1, but is of a higher molecular weight. Similarly, PEG-modified Methyl Violet 2B is closely related to Methyl Violet 2B, but is of a higher molecular weight. Methyl Violet 2B, itself, currently is exempted from the requirement of a tolerance under 40 CFR 180.1001.

Additional acute toxicity studies on the polymeric colorants of interest include skin and eye irritation studies. Primary dermal irritation studies in rabbits on PEG-modified FD&C Blue No. 1 show ''minimally irritating'' results and primary eye irritation studies in rabbits show ''practically non-irritating'' results. The dermal sensitization studies on PEG-modified FD&C Blue No. 1 show that this material is not a skin sensitizer. In addition, primary dermal irritation studies on the test material having slightly shorter side chain lengths than PEG-modified FD&C Blue No. 1, show no effects. Finally, primary dermal irritation studies in rabbits on PEG-modified Methyl Violet 2B show barely perceptible erythema on abraded sites only, and primary eye irritation studies in rabbits show ''non-irritating'' results.

2. *Genotoxicity. In Vitro* Transformation Studies and Mouse Lymphoma Forward Mutation Studies on PEG-modified FD&C Blue No. 1 both show that this test material is inactive. Furthermore, an Ames study on Methyl-PEG-modified FD&C Blue No. 1 shows non-mutagenic results. Mutagenicity studies have not been conducted on Methyl Violet 2B, PEG Analog.

3. *Reproductive and developmental toxicity. In Vitro* Transformation Studies and Mouse Lymphoma Forward Mutation Studies on PEG-modified FD&C Blue No. 1 both show that this test material is inactive. Furthermore, an Ames study on Methyl-PEG-modified FD&C Blue No. 1 shows non-mutagenic results. Mutagenicity studies have not been conducted on Methyl Violet 2B, PEG Analog.

4. *Chronic toxicity*. Chronic toxicity studies have not been conducted on the three colorants of interest; however, studies have been conducted on FD&C Blue No. 1, which is closely related to the FD&C Blue No. 1 PEG and methyl PEG analogs. For this substance, a chronic dietary No-Observed-Adverse-Effect Level (NOAEL) in mice has been shown to be 7,354 milligrams per kilogram body weight per day for males, and 8,966 milligrams per kilogram per day for females. A chronic dietary NOAEL for rats has been shown to be 1,072 for milligrams per kilogram body weight per day for males and 631 milligrams per kilogram body weight per day for females, showing a low order of chronic toxicity.

C. Aggregate Exposure

1. *Dietary exposure*. Dietary exposure to the polymeric colorants, if at all, will be at *de minimis* levels. The colorants are intended to be used as inert ingredients in pesticides that will be applied to seeds. (The purpose of the colorants is to signal users that the seeds have been treated with a pesticide that is not the subject of a tolerance or an exemption from tolerance.) Because the colorants are polymeric, they are not expected to be taken up by the growing plants. Indeed, a determination of the octanol/water partition coefficient for a test material identical to PEG-modified FD&C Blue No. 1, but with slightly longer side chain lengths, resulted in low values that demonstrate that the colorant would have little or no tendency to concentrate in the fatty portions of animals or in plants. Even assuming, however, that the polymeric colorants are taken up by growing plants, the potential dietary exposure to these materials is less than 0.6 parts per billion (ppb) of the diet. This estimate is based on data presented in Knott's Handbook for Vegetable Growers, O. Lorenz and D. Maynard (c1988), which provides data with respect to the ''Approximate Number of Seeds per Ounce and per Gram and Seeding Rates for Traditional Plant Densities,'' and ''Yields of Vegetable Crops.''

Although the calculated dietary exposure to the colorants is minuscule, it is important to note that even this extremely low calculated exposure clearly is a gross overestimate, given the polymeric nature of the colorants. Furthermore, although an acceptable daily intake (ADI) for the colorants of interest has not been established, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has established an ADI for FD&C Blue No. 1 of 5 mg/kg body weight/day, or 100 ppm of the diet. Furthermore, JECFA has established an ADI for PEG of 10 mg/kg/person/day, or 200 ppm of the diet. (See ''World Health Organization Technical Report Series'', Nos. 557 and 648.) The estimated dietary exposure to the colorants of interest is over two orders of magnitude below these ADIs for related compounds.

Currently, there are no established tolerances or exemptions from tolerance for any of the colorants. However, the colorants are simply polyethylene glycol-modified versions of dyes that currently are exempt from the requirement of a tolerance (i.e., FD&C Blue No. 1 and Methyl Violet 2B).

2. *Drinking water*. There is no available information regarding exposure to PEG-modified FD&C Blue No. 1, Methyl-PEG-modified FD&C Blue No. 1, or PEG-modified Methyl Violet 2B via drinking water. However, aerobic soil metabolism studies on PEG-modified FD&C Blue No. 1 and PEG-modified Methyl Violet 2B demonstrate that these colorants are ''inherently biodegradable.'' Furthermore, the results of aerobic soil metabolism studies on all three colorants show that between 19% and 25% of each colorant degrades within 42 days. Based on these results and the low use levels of the colorants, significant exposure to these colorants in drinking water is not anticipated. Furthermore, there is no established Maximum Concentration Level for the polymeric colorants in drinking water.

3. *Non-dietary exposure*. The proposed use of PEG-modified FD&C Blue No. 1, Methyl-PEG-modified FD&C Blue No. 1, and PEG-modified Methyl Violet 2B involves either application to turf grass seeds or application to seeds grown in an agricultural environment. Thus, there is no potential for significant non-occupational exposure of the colorants to the general population.

D. Cumulative Effects

There is no reason to suspect that toxic effects of PEG-modified FD&C Blue No. 1, Methyl-PEG-modified FD&C Blue No. 1, PEG-modified Methyl Violet 2B would be cumulative with those of any other pesticide inert or active chemical, and there are no data to indicate that this would be the case. Thus, Milliken considers it appropriate to evaluate the potential risks of the colorants solely in the context of the aggregate exposure assessment.

E. Safety Determination

1. *U.S. population*. Data from acute toxicity studies show FD&C Blue No. 1, PEG and Methyl PEG Analogs and PEG-modified Methyl Violet 2B to be of a very low order of toxicity. Furthermore, two compounds that are closely related to the colorants of interest, FD&C Blue No. 1 and Methyl Violet 2B, currently are exempt from the requirement of a tolerance under 40 CFR 180.1001 paragraphs (b) and (c), respectively. In addition, FD&C Blue No. 1 is cleared by FDA for use in coloring food and drugs. Use of the polymeric colorants of interest as inert ingredients in pesticides applied to turf grass seeds and seeds for edible plants such as beans, squash, and soybeans is not expected to result in significant dietary exposures. Furthermore, there currently are no other registered pesticidal uses in which these polymeric colorants are used.

Because of the *de minimis* potential dietary exposures to the polymeric colorants, there are no dietary risk concerns associated with the intended use of the colorants, and there is a reasonable certainty that no harm will result from such use.

2. *Infants and children*. The toxicity and exposure data in the petition are sufficiently complete to adequately address the potential for additional sensitivity to infants and children. Specifically, as discussed above, developmental and reproductive effects studies on PEG-modified and Methyl-PEG-modified FD&C Blue No. 1 have shown no developmental/reproductive effects. Based on these data, together with the low potential dietary exposure to the colorants, there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to PEG-modified FD&C Blue No. 1, and Methyl-PEG-modified FD&C Blue No. 1. Furthermore, although developmental effects studies have not been conducted on PEG-modified Methyl Violet 2B, the potential dietary exposure to this colorant is sufficiently low as to establish that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to PEG-modified Methyl Violet 2B.

F. International Tolerances

There are no Codex maximum residue levels established for residues of PEG-modified FD&C Blue No. 1, Methyl-PEG-modified FD&C Blue No. 1, or PEG-modified Methyl Violet 2B. (Amelia Acierto)

[FR Doc. 97–23097 Filed 8–28–97; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY.

[OPPTS–00222; FRL–5740–3]

Regional Training Courses on EPCRA Section 313 Reporting Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA will hold a series of 2–day training courses on the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) section 313. The training courses are intended primarily to introduce the reporting requirements to the staffs of recently added industry groups that will be subject to the reporting requirements of section 313 (62 FR 23834, May 1, 1997)(FRL–5578–3) beginning on January 1, 1998.

DATES: For the dates of the training courses see ''SUPPLEMENTARY INFORMATION.''

ADDRESSES: For the locations of the training courses see ''SUPPLEMENTARY INFORMATION.''

FOR FURTHER INFORMATION CONTACT: Michael Hart (202) 260–1576, or the EPCRA Information Hotline at (800) 535–0202. To register call the Hotline number.

SUPPLEMENTARY INFORMATION: EPA will hold a series of 2–day training courses on the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) section 313, which are intended primarily to introduce the reporting requirements to facility staff for facilities recently added (62 FR 23834 May 1, 1997). These newly added industries include Metal Mining (SIC code 10, except 1011, 1081, and 1094), Coal Mining (SIC code 12, except 1241), Electric Utilities (SIC codes 4911, 4931, and 4939 [limited to facilities that combust coal and/or oil for the purpose of generating electricity for distribution in commerce]), Commercial Hazardous Waste Treatment (SIC codes 4953 [limited to facilities regulated under RCRA Subtitle C, 42 U.S.C. section 6921 et seq.]), Solvent Recovery Services (SIC code 7389 [limited to facilities primarily engaged in solvents recovery services on a contract or fee basis]), Chemical and Allied Products—Wholesale (SIC code 5169), and Petroleum Bulk Terminal and Stations—Wholesale (SIC code 5171). The training course consists of a series of presentations covering the basic requirements of EPCRA section 313 and the sections of the Pollution Prevention Act of 1990 (PPA) that relate to the EPCRA section 313 requirements. A variety of hands-on exercises using the EPCRA section 313 reporting Form R and associated guidance materials will be used to help participants understand the EPCRA section 313 reporting process. Guidance documents being developed to assist the new industries comply with EPCRA section 313 and PPA requirements will be made available at the training sessions. Persons who should consider attending are staff from facilities which operate in the newly added industry sectors, staff from facilities that may be affected by the recent changes to EPCRA section 313, and Federal and private sector facility staff responsible for completing their facilities TRI reporting form(s), and consulting firms who may be assisting them.

Registration for the training courses will be taken on a first-come-first-served basis until 2–weeks prior to the start date of each course. EPA intends to present sector-specific training modules for each of the new industry sectors added, but this may be modified for each of the training sessions based on responses received. There is limited space available.

To register, contact The EPCRA Information Hotline at the telephone number listed under ''FOR FURTHER INFORMATION CONTACT.'' When registering, give your name, postal (and electronic, if any) mailing address, telephone and fax numbers, and the industry sector in which you are interested in receiving particular training. Guidance documents for each of the newly added industry groups will be made available at each of the training sessions whether the training session contains a reporting module for that industry or not. Notification will be sent to each applicant regarding their acceptance for the training session. There is no registration fee for this training. If there is insufficient interest in any of the course, those courses may be canceled. Registrants will be notified in the event a training course is canceled. The Agency bears no responsibility for attendees' decision to