SUMMARY: A meeting of the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee) will be held on June 8–10, 1998, in Washington, DC. At this meeting, the NAC/AEGL Committee will address the various aspects of the acute toxicity and the development of Acute Exposure Guideline Levels (AEGLs) for the following chemicals: acrolein, carbon tetrachloride, chloroform, crotonaldehyde, hydrogen sulfide, nickel carbonyl, nitrogen oxides, peracetic acid, propylene imine, and propylene oxide.

DATES: A meeting of the NAC/AEGL Committee will be held from 10 a.m. to 5 p.m. on Monday, June 8, 1998; from 8:30 a.m. to 5 p.m. on Tuesday, June 9, 1998; and from 8:30 a.m. to 1 p.m. on Wednesday, June 10, 1998.

ADDRESSES: The meeting will be held at the National Endowment for the Arts, 1100 Pennsylvania Ave., NW., Rm. M09, Washington, DC 20506 (located in the Old Post Office Building, across the street from the Federal Triangle Metro stop).

FOR FURTHER INFORMATION CONTACT: Paul S. Tobin, Designated Federal Officer (DFO), Office of Prevention, Pesticides, and Toxic Substances (7406), 401 M St., SW., Washington, DC 20460; (202) 260–1736; e-mail: tobin.paul@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Electronic Availability

Internet

Electronic copies of this notice and various support documents are available from the EPA Home Page at the **Federal Register**—Environmental Documents entry for this document under ''Laws and Regulations'' (http://www.epa.gov/fedrgstr/).

Fax-On-Demand

Using a faxphone call (202) 401–0527 and select item 4800 for an index of items in this category.

II. Meeting Procedures

For further information on the meeting, the meeting agenda, the submission of information, or presentation of information on chemicals to be discussed, contact the DFO.

The meeting of the NAC/AEGL Committee will be open to the public. Oral presentations or statements by interested parties will be limited to 10 minutes. Interested parties should contact the DFO to schedule statements or presentations before the NAC/AEGL Committee. Since seating for outside observers may be limited, those wishing to attend the meeting as observers should also contact the DFO as soon as possible to ensure adequate seating arrangements. Direct all inquiries regarding oral presentations, oral statements, submission of written statements, or chemical-specific information to the DFO.

Another meeting of the NAC/AEGL Committee is expected to be held September 1998, but the exact date and meeting location are not yet determined. It is anticipated that the chemicals to be addressed at this meeting will include, but are not limited to, the following: cylohexylamine, ethylene diamine, glycol ether acetate, HFC–134a, HCFC–141b, methyl isocyanate, piperidine sulfur dioxide, sulfur trioxide, and sulfuric acid. Direct inquiries regarding the submission of data, written statements, or chemical-specific information on the chemicals listed for the September 1998 meeting to the DFO as soon as possible to allow for consideration of this information in the preparation of the NAC/AEGL Committee materials.

List of Subjects

Environmental protection, Hazardous substances, Health.

Dated: May 14, 1998.

William H. Sanders, III,

Director, Office of Pollution Prevention and Toxics.

[FR Doc. 98–13445 Filed 5–19–98; 8:45am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–793; FRL–5773–2]

Notice of Filing of Pesticide Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of the pesticide chemical pymetrozine, in or on various food commodities.

DATES: Comments, identified by the docket control number PF–793, must be received on or before June 19, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), 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 product manager listed in the table below:

Product Manager	Office location/telephone number	Address
Leonard Cole	Rm. 211, CM #2, 703–305–5412, e-mail:cole.leonard@epamail.epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA

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–793] (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 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number (insert docket number) 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: May 6, 1998.

James Jones,

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.

Norvartis Crop Protection, Inc.

PP 8F4929

EPA has received a pesticide petition (PP 8F4929) from Norvartis Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419–8300 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 Pymetrozine in or on the raw agricultural commodity cucumbers, fruiting vegetables, potatoes, hops at 0.02, 0.05 parts per million. 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 CGA–215944 in plants is understood for the purposes of the proposed tolerance. Studies in rice, tomatoes, cotton and potatoes gave similar results. Identified metabolic pathways have demonstrated that pymetrozine is the residue of concern for tolerance setting purposes.

2. *Analytical method*— i. *Crops*. Novartis has submitted two analytical methods for the determination of pymetrozine and its major crop metabolite, in crop substrates. For both methods, the limit of detection (LOD) is 1.0 ng and the limit of quantitation (LOQ) is 0.02 ppm. Samples are extracted using acetonitrile: 0.05M sodium borate and an aliquot is taken for each method. The aliquots were cleaned up with solid-phase and/or liquid-liquid partitions and analyzed by HPLC with column-switching and UV detection. Both methods have undergone independent laboratory validation. The pymetrozine Analytical Method is proposed as the tolerance enforcement method.

ii. *Livestock*. Novartis has also submitted analytical methods for the determination of pymetrozine in eggs, milk and poultry, dairy and goat tissues, and for its major livestock metabolite in dairy and goat tissues and milk. This method also accounts for a phosphate conjugate, which is a significant metabolite found only in milk. The LOD for the analytical method is 1.0 ng and the LOQ is 0.01 ppm. Samples are extracted using acetonitrile: Water, cleaned up with solid-phase and liquid-liquid partitions, and analyzed for pymetrozine by HPLC with column switching and UV detection. The LOD for the metabolite method is 1.5 ng and the is LOQ of 0.01 ppm. Samples are extracted using methanol: Water. Milk samples are heated to hydrolyze the phosphate conjugate, and all samples are cleaned up with solid-phase partitions and analyzed by HPLC with UV detection. The parent Analytical Method has successfully undergone independent laboratory validation.

3. *Magnitude of residues*—i. *Cucurbits*. Twenty-two field trials were conducted in 13 states representing typical fruiting vegetables growing areas in the United States, including Arizona, California, Florida, Georgia, Indiana, Michigan, New York, North Carolina, Ohio, Oregon, South Carolina, and Texas. Cantaloupes, summer squash, and cucumbers were treated with two post foliar applications of pymetrozine 50WG at 21 and 14 days prior to harvest of mature fruit using a 1X rate of 80 g a.i./A per application (160 g a.i. or 0.35 lb a.i.per a). Samples of summer squash and cucumbers from early harvest harvest intervals (pre-harvest interval (PHI) < 14 days) were collected to demonstrate decline of residues of pymetrozine.

Residue data were generated for pymetrozine for tolerance setting and dietary exposure estimates. Data was generated for a major metabolite for dietary exposure purposes only as this metabolite does not need to be part of the tolerance expression. No pymetrozine residues were found in cantaloupes treated at the 1X rate and harvested at the target PHI of 14 days. Maximum GS–23199 residues of 0.02 ppm were found in only 1 of 16 cantaloupe samples. The maximum pymetrozine residues found in summer squash samples treated at the 1X rate were 0.02 ppm in a sample harvested at 0–day PHI. No pymetrozine residues were found in any 3–day, 7–day, or 14–day sample of squash treated at the 1X rate. No metabolite residues were found in any summer squash sample at any PHI. No pymetrozine or metabolite residues were found in any sample of cucumbers treated at the 1X rate and harvested at 14 days PHI.

No residues of pymetrozine are expected in cucurbits vegetables treated at the 1X rate and harvested 14 days after the last application.

ii. *Fruiting vegetables*. Seventeen field trials were conducted in 12 states representing typical fruiting vegetable growing areas in the United States, including California, Florida, Indiana, Maryland, Michigan, New Jersey, New Mexico, North Carolina, Ohio, Pennsylvania, Tennessee, and Texas. Tomatoes and peppers were treated

with two post foliar applications of pymetrozine 50 WP 21 and 14 days prior to harvest of mature fruit using a 1X rate of 80 g active ingredient/acre (a.i./A), a 2X rate of 160 g a.i./A, a 3X rate of 240 g a.i./A, and a 5X rate of 400 g a.i./A per application. Samples from early harvest intervals (pre-harvest interval < 14 days) were collected to demonstrate decline of residues of pymetrozine. Mature fruit from two tomato field trials were processed under simulated commercial practice.

Residue data were generated for pymetrozine for tolerance setting and dietary exposure estimates. Data was generated for the major metabolite for dietary exposure purposes only as this metabolite does not need to be part of the tolerance expression. Pymetrozine residues were found in 0– and 3–day PHI samples of tomatoes treated at the 1X rate, but in none of the 7–day PHI 1X samples analyzed. No pymetrozine residues were found in tomatoes treated at the 1X rate and harvested at the target PHI of 14 days. No residues of the metabolite were found in samples harvested with 0–, 3–, or 7–day PHI, but metabolite residues of 0.02 ppm were found in 1 of 22 1X tomato samples harvested with a 14–day PHI.

All analyzed tomato samples treated at exaggerated rates were harvested with a 14–day PHI. No pymetrozine residues were found in any 2X tomato sample. The maximum pymetrozine residues found in 3X and 5X samples were 0.04 ppm and 0.10 ppm. The maximum residues found in 2X, 3X, and 5X samples were 0.02 ppm, 0.08 ppm, and 0.10 ppm.

All analyzed processed tomato fractions were from tomatoes harvested with a 14–day PHI. No residues of pymetrozine were found in any processed fraction from tomatoes treated at exaggerated rates. No 1X processed tomato fraction samples were analyzed. The maximum residues of metabolite found in tomato processed fractions were 0.4 ppm in juice from tomatoes treated at the 5X rate.

All pepper samples analyzed were treated at the 1X rate. Pymetrozine residues of 0.04 ppm were found in 1 of 20 pepper samples harvested at a 14–day PHI. Pymetrozine residues were found in all eight 0–day PHI samples, but in none of the four 3–day or 7–day PHI samples analyzed. No metabolite residues were found in any pepper sample at any PHI.

Little or no residues of pymetrozine are expected in fruiting vegetables treated at the 1X rate and harvested 14 days after the last application.

Tuberous and corm vegetables. Sixteen field trials were conducted in 13 States representing typical potato growing areas in the United States, including Idaho, Washington, Oregon, California, Florida, North Dakota, Minnesota, North Carolina, Wisconsin, Colorado, Maine, New York, and Michigan. Potatoes were treated with two foliar applications of pymetrozine 50 WP made 21 and 14 days prior to first harvest using a 1X rate of 40 g a.i./A, a 3X rate of 120 g a.i./A, and a 5X rate of 400 g a.i./A per application. Samples from early harvest intervals (PHI < 14 days) were collected to demonstrate decline of residues of pymetrozine.

Residue data was generated for pymetrozine for tolerance setting and dietary exposure estimates. Data was generated for the major metabolite for dietary exposure purposes only as this metabolite does not need to be part of the tolerance expression. No residues of pymetrozine or GS–23199 were found in potatoes or processed fractions for any application rate at any PHI in this study.

iii. *Tobacco*. Five field trials were conducted in five states representing typical tobacco growing areas in the United States, including North Carolina, South Carolina, Tennessee, Kentucky, and Virginia. Tobacco was treated with two post foliar applications of pymetrozine 50 WP 21 and 14 days prior to harvest of mature leaves. Rates of 20 g a.i./A and 40 g a.i./A per application were used. Samples from early harvest intervals (PHI < 14 days) were collected to demonstrate decline of residues of pymetrozine.

The maximum residues of pymetrozine found in green leaves of tobacco harvested at 14 days after last application were 0.05 ppm. The maximum residues of metabolite found in green leaves harvested at 14 days after last application were 0.04 ppm. The maximum Detectable residues of pymetrozine found in 23 of 24 samples of cured leaves of tobacco harvested at 14 days after last application was 0.39 ppm. The maximum residues of metabolite found in cured leaves harvested at 14 days after last application were 0.20 ppm.

In decline studies, detectable residues of pymetrozine were found to decrease with increasing PHI in green leaves. Maximum average metabolite GS–23199 residues were found in 3– and 7– day samples with the lowest average residues in 14–day samples.

iv. *Hops*. Data from eight field trials, conducted in Germany, were submitted August 6,1996. The residue data support a tolerance of 5.0 ppm with a 14–day PHI.

v. *Livestock*. A three-level dairy feeding study was conducted using pymetrozine as the test substance. Holstein dairy cows were dosed daily with pymetrozine at levels equivalent to 0 (Control), 1.0 ppm, 3.0 ppm and 10 ppm. These rates represents 8, 24 and 80 times the maximum expected contribution to the diet. This study was designed to provide data concerning the level of residues of pymetrozine, as pymetrozine and CGA–313124, in milk and tissues which could occur as a result of feeding crops treated with pymetrozine to dairy cows. The results are used to estimate the transfer of residues from the diet to the tissues and milk of livestock.

No detectable residues of pymetrozine or CGA–313124 were observed in samples of liver, kidney, perirenal fat, omental fat, round muscle, or tenderloin muscle from cows dosed with 10 ppm (80X) pymetrozine. No detectable residues of pymetrozine were observed in samples of milk from cows dosed with 10 ppm (80X), 3 ppm (24X), or 1 ppm (8X) pymetrozine at any sampling interval. Detectable residues of CGA–313124 occurred only in milk samples from 80X dosed cows at a maximum level of 0.05 ppm. These results indicate that there is no need to establish a meat and milk tolerance.

B. Toxicological Profile

1. *Acute toxicity*. Pymetrozine has low acute toxicity. The oral LD_{50} in rats is > 5,820 milligrams per kilogram (mg/kg) for males and females, combined. The rat dermal LD_{50} is > 2,000 mg/kg and the rat inhalation LC_{50} is > 1.8 mg/L air. Pymetrozine is not a skin sensitizer in guinea pigs and does not produce dermal irritation in rabbits. It produces minimal eye irritation in rabbits. End-use water-dispersible granule formulations of pymetrozine have similar low acute toxicity profiles.

2. *Genotoxicty*. Pymetrozine did not induce point mutations in bacteria (Ames assay in *Salmonella typhimurium* and *Escherichia coli*) or in cultured mammalian cells (Chinese hamster V79) and was not genotoxic in an *in vitro* unscheduled DNA synthesis assay in rat hepatocytes. Chromosome aberrations were not observed in an *in vitro* test using Chinese hamster ovary cells and there were no clastogenic or aneugenic effects on mouse bone marrow cells in an *in vivo* mouse micronucleus test. These studies show that pymetrozine is not genotoxic.

3. *Reproductive and developmental toxicity*. In a teratology study in rats, pymetrozine caused decreased body weights and food consumption in females given 100 and 300 mg/kg/day during gestation. This maternal toxicity was accompanied by fetal skeletal

anomalies and variations consistent with delayed ossification. The no-observed-effect level (NOEL) for maternal and fetal effects in rats was 30 mg/kg/day. A teratology in rabbits showed that pymetrozine caused maternal death and reduced body weight gain and food consumption at 125 mg/kg/day (highest dose tested). Maternal toxicity was accompanied by embryo- and feto-toxicity (abortion in one female and total resorptions in two females). Body weight and food consumption decreases, early resorptions and postimplantation losses were also observed in maternal rabbits given 75 mg/kg/day. There was an increased incidence of fetal skeletal anomalies and variations at these maternally toxic doses. The NOEL for maternal and fetal effects in rabbits was 10 mg/kg/day. Pymetrozine is not teratogenic in rats or rabbits. In a two generation reproduction study in rats, parental body weights and food consumption were decreased, liver and spleen weights were reduced and histopathological changes in liver, spleen and pituitary were observed at 2,000 ppm (highest dose tested). Liver hypertrophy was observed in parental males at 200 ppm (approximately 10–40 mg/kg/day). Reproductive parameters were not affected by treatment with pymetrozine. The NOEL for reproductive toxicity is 2,000 ppm (approximately 110–440 mg/kg/day). Offspring body weights were slightly reduced at 2,000 and 200 ppm and eye opening was slightly delayed in pups at 2,000 ppm. Effects on offspring were secondary to parental toxicity. The NOEL for toxicity to adults and pups is 20 ppm (approximately 1–4 mg/kg/day).

4. *Subchronic toxicity.* Pymetrozine was evaluated in 13–week subchronic toxicity studies in rats, dogs and mice. Liver, kidneys, thymus and spleen were identified as target organs. The NOEL was 500 ppm (33 mg/kg/day) in rats and 100 ppm (3 mg/kg/day) in dogs. In mice, increased liver weights and microscopical changes in the liver were observed at all doses tested. The NOEL in mice was < 1,000 ppm (198 mg/kg/day). No dermal irritation or systemic toxicity occurred in a 28–day repeated dose dermal toxicity study with pymetrozine in rats given 1,000 mg/kg/day. Minimum direct dermal absorption (1.1%) of pymetrozine was detected in rats over a 21 hour period of dermal exposure. Maximum radioactivity left on or in the skin at the application site and considered for potential absorption was 11.9%.

5. *Chronic toxicity*. Based on chronic toxicity studies in the dog and rat, a reference dose (RfD) of 0.0057 mg/kg/day is proposed for pymetrozine. This RfD is based on a NOEL of 0.57 mg/kg/day established in the chronic dog study and an uncertainty factor of 100 to account for interspecies extrapolation and interspecies variability. Minor changes in blood chemistry parameters, including higher plasma cholesterol and phospholipid levels, were observed in the dog at the lowest-observed-effect level (LOEL) of 5.3 mg/kg/day. The NOEL established in the rat chronic toxicity study was 3.7 mg/kg/day, based on reduced body weight gain and food consumption, hematology and blood chemistry changes, liver pathology and biliary cysts.

6. *Animal metabolism*. The metabolism of pymetrozine (CGA–215944) in the rat is well understood. Metabolism involves oxidation of the 5-methylene group of the triazine ring yielding 4,5-dihydro-5-hydroxy-6-methyl-4-[(3-pyridinylmethylene)amino]-1,2,4-triazin-3(2H)-one (CGA–359009). Oxidation of the methyl substituent of the triazine ring led to 4,5-dihydro-6-(hydroxymethyl)-4-[(3-pyridinylmethylene)amino]-1,2,4-triazin-3(2H)-one (CGA–313124) which was further oxidized to the corresponding carboxylic acid, 4,5-dihydro-6-carboxy-4-[(3-pyridinylmethylene)amino]-1,2,4-triazin-3(2H)-one. Hydrolysis of the enamino bridge yielded 4-amino-6-methyl-1,2,4-triazin-3,5(2H,4H)-dione (CGA–294849). This was further degraded to 6-methyl-1,2,4-triazin-3,5(2H,4H)-dione (METABOLITE). Hydrolysis of the enamino bridge of CGA–215944 produced CGA–215525 which undergoes either acylation (CGA–259168) or deamination yielding 4,5-dihydro-6-methyl-1,2,4-triazin-3(2H)-one (CGA–249257). Hydrolysis of the enamino bridge also formed 3-pyridinecarboxaldehyde (CGA–300407), nicotinic acid (CGA–180777), nicotinamide (CGA–180778), 3-pyridinemethanol (CGA–128632) and 1,6-dihydro-1-methyl-6-oxo-3-pyridinecarboxamide. Identified metabolic pathways in animals and plants are similar.

7. *Metabolite toxicology*. The residue of concern for tolerance setting purposes is the parent compound. Metabolites of pymetrozine are considered to be of equal or lesser toxicity than the parent.

8. *Endocrine disruption*. Pymetrozine does not belong to a class of chemicals known or suspected of having adverse effects on the endocrine system. There is no evidence that pymetrozine has any effect on endocrine function in developmental and reproduction studies. Furthermore, histological investigation of endocrine organs in chronic dog, rat and mouse studies did not indicate that the endocrine system is targeted by pymetrozine.

C. Aggregate Exposure

1. *Food*. For purposes of assessing the potential dietary exposure under the proposed tolerances, Novartis has estimated aggregate exposure based on exposure from residues of 0.05 ppm on fruiting vegetables, 0.02 ppm on cucurbits, 0.02 ppm on potatoes and 5 ppm on hops. A 100% market share was assumed.

2. *Drinking water.* Another potential source of exposure of the general population to pymetrozine is via residues in drinking water. Pymetrozine is not expected to contaminate drinking water based on its environmental attributes and the low application rates applied. Pymetrozine breaks down relatively quickly in the environment by a wide variety of mechanisms and degradation pathways. Leaching studies showed that pymetrozine is tightly bound to soil and is unlikely to leach in the field. Field dissipation studies show little movement beyond the uppermost soil horizon.

3. *Non-dietary exposure*. There are no other uses currently registered for pymetrozine. The proposed uses involve application of pymetrozine to crops grown in an agricultural environment. There are no proposed uses which would be expected to result in residential exposure of pymetrozine. Therefore, there is no potential for non-occupational exposure to the general population. is not expected to be significant.

D. Cumulative Effects

The potential for cumulative effects of pymetrozine and other substances that have a common mechanism of toxicity has also been considered. Pymetrozine belongs to a new chemical class known as pyridine azomethines. It exhibits a unique mode of action which can be characterized as nervous system inhibition of feeding behavior. It does not have a general toxic or paralyzing effect on insects, but selectively interferes with normal feeding activities by affecting nervous system regulation of fluid intake. There is no reliable information to indicate that toxic effects produced by pymetrozine would be cumulative with those of any other chemical including another pesticide. Therefore, Novartis believes it is appropriate to consider only the potential risks of pymetrozine in an aggregate risk assessment.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions and the proposed RfD described above, the aggregate exposure to pymetrozine will utilize 3.78% 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 exposure over a lifetime will not pose appreciable risks to human health. Therefore, Novartis concludes that there is a reasonable certainty that no harm will result from aggregate exposure to pymetrozine residues.

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

In a teratology study in rats, developmental toxicity anomalies and variations associated was observed only at maternally toxic doses. Similarly, in a rabbit teratology study, was observed only at maternally toxic doses. The NOELs in the rat and rabbit teratology studies were 30 and 10 mg/kg/day, respectively. In the two-generation reproduction study, there were no effects on reproductive parameters. Offspring body weights were slightly reduced and eye opening was slightly delayed at dose levels producing parental toxicity. The NOEL for parental and offspring toxicity was 20 ppm (approximately 1–4 mg/kg/day).

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 requirements, the database relative to pre- and post-natal effects for children is complete. Further, for pymetrozine, the NOEL of 0.57 from the chronic feeding study in dogs, which was used to calculate the RfD (0.0057 mg/kg/day), is already lower than the developmental NOELs (30 and 10 mg/kg/day) from the teratogenicity studies in rats and rabbits by a factor of more than tenfold. In the pymetrozine rat reproduction study, the mild nature of the effects observed (decreased body weight) at the systemic LOEL (10–40 mg/kg/day) and the fact that the effects were observed at a dose that is more than 10 times greater than the NOEL in the chronic dog study (0.57 mg/kg/day) suggest that there is no additional sensitivity for infants and children. Therefore, it is concluded that an additional uncertainty factor is not warranted to protect the health of infants and children and that an RfD of 0.0057 mg/kg/day based on the chronic dog study is appropriate for assessing aggregate risk to infants and children from pymetrozine.

Using the exposure assumptions described above, the percent of the RfD that will be utilized by aggregate exposure to residues of pymetrozine is 0.43% for nursing infants less than 1 year old, 1.49% for non-nursing infants, 3.44% for children 1–6 years old and 2.72% for children 7–12 years old. Therefore, based on the completeness and reliability of the toxicity database, Novartis concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to pymetrozine residues.

F. International Tolerances

There are no Codex maximum levels established for residues of pymetrozine.

[FR Doc. 98–13447 Filed 5–19–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–804; FRL–5788–8]

Westvaco Corporation; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by the docket control number PF–804, must be received on or before June 19, 1998.

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Divison (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, 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. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Bipin C. Gandhi, Registration Support Branch, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 4-W53, Crystal Station ı1, 2800 Jefferson Davis Highway, Arlington, VA 22202, (703) 308–8380; e-mail: gandhi.bipin@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemical 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 this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data 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–804] (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