be in the drinking water. Plant viruses are a natural component of the environment and are present in soil and water. Consequently, Cornell University believes that coat proteins produced as plant-pesticides would represent a negligible addition to those existing in drinking water.

2. *Non-dietary exposure.* Cornell University believes that non-dietary exposure to engineered coat proteins will be minimal to non-existent because the coat protein is expressed only within the plant tissues.

E. Cumulative Exposure

Exposure through other pesticides and substances with the common mode of toxicity as this pesticide. Cornell University believes that due to the lack of toxicity/pathogenicity associated with plant viruses or plant viral coat proteins, cumulative effects with other pesticides and substances will be non-existent.

F. Safety Determination

1. *U.S. population.* There is no known toxicity associated with coat proteins from plant viruses. Consequently, a safety assessment is not needed for these proteins. Given the long history of mammalian consumption of the entire plant virus particle in foods, without any adverse human health effects, Cornell University reasonably believes that consumption of a noninfectious component of the PRV plant virus is safe. There are no known data that indicate aggregate exposure to plant viral coat proteins under normal conditions will result in harm to any person.

2. *Infants and children.* Viral coat proteins are ubiquitious in foods, including those foods consumed by infants and children. Moreover, there is not reason to believe that plant viral coat proteins are likely to occur in different amounts in foods, consumed by children and infants. Further, there is no scientific evidence that viral coat proteins used as plant-pesticides would have a different effect on children that on adults. Viral coat proteins are not toxic and, therefore, Cornell University believes with reasonable certainty that no harm will result to infants and children from aggregate exposure to coat proteins from plant viruses.

G. Existing Tolerances

No tolerance or exemption from tolerance has been previously granted for PRV coat protein.

H. International Tolerance

International tolerance levels for Papaya Ringspot Virus Coat Protein have not been determined. However, papaya fruit from trees infected with papaya ringspot virus are consumed by numerous people throughout the world.

Cornell University concludes that plant viruses, including PRV coat proteins, are not harmful to humans, and that there is a reasonable certainty that no harm will result from aggregate exposure to Coat Protein of Papaya Ringspot Virus and the genetic material necessary for its production, including all anticipated dietary exposures and all other non-occupational exposures. Accordingly, Cornell University believes that the PRV coat protein qualifies for an exemption from the requirement of a tolerance in or on all raw agricultural commodities.

[FR Doc. 97–8396 Filed 4–1–97; 8:45 am]
BILLING CODE 6560–50–F

[PF–723; FRL–5593–9]

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 agricultural commodities.

DATES: Comments, identified by the docket control number PF–723, must be received on or before May 2, 1997.

ADDRESSES: By mail submit written comments to: Public Response and Program Resources Branch, Field Operations Divison (7505C), 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
Connie Welch (PM 21) ..	Rm. 227, CM #2, 703–305–6226, e-mail:welch.connie@epamail.epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA
Cynthia Giles-Parker (PM 22).	Rm. 229, CM #2, 703–305–5540, e-mail: giles-parker.cynthia@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 raw agricultural 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 grantinig 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–723 (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 (insert docket number) and appropriate petition number. Electronic comments on this proposed rule 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: March 24, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Below summaries of the pesticide petitions are printed. The summaries of the petitions were prepared by the petitioners. 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. Bayer's Corporation

PP 6F4631

EPA has received a pesticide petition (PP 6F4631) from Bayer Corporation, 8400 Hawthorne Road, Kansas City, MO 64120–0013, 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 the herbicide, FOE 5043, *N*-(4-Fluorophenyl)-*N*-(1-methylethyl)-2[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide in or on the raw agricultural commodities, field corn grain at 0.05 parts per million (ppm), field corn forage at 0.4 ppm, field corn stover (fodder) at 0.4 ppm, soybean seed at 0.1 ppm, milk at 0.01 ppm, meat at 0.05 ppm, and meat byproducts at 0.05 ppm. The proposed analytical method is gas chromatography/mass spectrometry with selected ion monitoring. (PM 22)

1. *Chemical uses.* FOE 5043 use on field corn and soybeans provides selective weed control for a wide spectrum of annual grasses and small-seeded broadleaf weeds, with exceptional strength on barnyard grass, large crabgrass, fall panicum and foxtail species. Application technique: Products containing FOE 5043 can be applied preplant surface, preplant incorporated, or preemergence for control of emerging weeds. Applications can be made up to 45 days before planting. Applications may be made using standard low pressure ground herbicide boom sprayers equipped with suitable nozzles and screens. The products containing FOE 5043 may be applied either as a single or a split application. Application rates range from 0.442 to 0.884 pounds active ingredient (a.i.) of FOE 5043 per acre depending on the soil texture and soil organic matter content. Tank mix combinations with selected products may provide additional weed control.

2. *FOE 5043 Safety.* Bayer has submitted over 65 separate toxicology studies in support of tolerances for FOE 5043. Among the submissions, a finding of particular interest was the observation that in the long-term data compiled for FOE 5043, provided no indications of a potential to induce either carcinogenic or reproductive signs of toxicity. In addition, developmental no-observed-adverse effects levels (NOAELs) of 25 milligrams body weight per day (mg/kg bwt/day) were established for both the rat and rabbit.

The following mammalian toxicity studies have been conducted to support the tolerance of AXIOM DF (contains FOE 5043 and metribuzin):

i. A rat acute oral study with an LD_{50} of 2,347 mg/kg (male) and 2,027 mg/kg (female).

ii. A rabbit acute dermal with an LD_{50} of > 2,000 mg/kg.

iii. A rat acute inhalation with an LD_{50} of > 977 mg/m^3.

iv. A primary eye irritation study in the rabbit which showed mild irritation.

v. A primary dermal irritation study which showed no irritation.

vi. A primary dermal sensitization study which showed no sensitization.

The following mammalian toxicity studies, derived from exposure to the technical form of the chemical, have been conducted to support the tolerance of FOE 5043:

i. A rat acute oral study with an LD_{50} of 1,617 mg/kg (male) and 589 mg/kg (female).

ii. A rat acute dermal LD_{50} of 2,000 mg/kg bwt.

iii. A rat acute inhalation LC_{50} of 3,740 mg/m^3 (male and female).

iv. A primary eye irritation study in the rabbit which showed no irritation.

v. A primary dermal irritation study which showed no irritation.

vi. A primary dermal sensitization study which showed no sensitization.

vii. An acute neurotoxicity study with a no-observed effect level (NOEL) for FOB, motor and locomotor activity of 75 mg/kg bwt/day for males and females.

viii. A 90–day feeding study in the rat with a NOEL of 1.7 mg/kg bwt/day.

ix. A 90–day subchronic neurotoxicity study in the rat with a neurotoxicity and overall NOEL of 120 ppm.

x. A 24–months chronic feeding/oncogenicity study in the rat with an overall NOEL of 1.2 mg/kg bwt/day in males and females based on liver, kidney, hematologic and thyroid effects. There was no evidence of an oncogenic response.

xi. A 90–day feeding study in dogs with a NOEL of 50 ppm, based on liver hematology, and thyroid effects.

xii. A 12–month feeding study in dogs with a NOEL of 40 ppm, based on hematology and thyroid effects.

xiii. A mouse oncogenicity study which provided no evidence of oncogenicity.

xiv. An oral teratology study in the rat with maternal and developmental NOAELs of 25 mg/kg bwt/day.

xv. An oral teratology study in the rabbit with maternal and fetal NOELs of 5 and 25 mg/kg bwt/day respectively.

xvi. An two-generation reproduction study in the rat with a NOEL for reproductive and parental toxicity of 500 and 20 ppm, respectively.

xvii. Ames assay: Negative

xviii. Unscheduled DNA synthesis: Negative

xix. Mouse Micronucleus Assay: Negative.

3. *Threshold effects— chronic effects.* Based on the available chronic toxicity data, Bayer believes the Reference Dose (RfD) for FOE 5043 should be 0.0114 mg/kg/day. The RfD for FOE 5043 is based on a 1 year chronic toxicity study in the dog with a threshold No Observed Effect Level (NOEL) of 1.14 mg/kg/day and an uncertainty factor of 100.

Acute toxicity. EPA recently proposed a tiered approach to estimate acute dietary exposure. The methods proposed by the EPA were reviewed and supported by the FIFRA Scientific Advisory Panel (SAP, 1995). EPA's Tier 1 method is based on the assumption that residue concentrations do not vary. The analysis assumes that all residues have the same magnitude, typically the highest field trial residue or tolerance value. This value is assumed for all

points along the consumption distribution, resulting in a distribution of dietary exposure.

For the acute analysis for FOE 5043, a Tier 1 analysis was conducted for the overall U.S. population, infants, children 1 to 6 years of age, females 13 years and older, and males 13 years and older. Using the NOEL of 138 mg/kg derived from the acute oral toxicity study in rats, the following margins of exposure were calculated (margins of exposure of 100 or more are considered satisfactory):

Population Group	Margin of Exposure
U.S. Population-All Seasons.	94,741
Infants	64,986
Children 1 to 6	76,494
Women 13 to 50 years old	191,418
Men 13 years and older	109,805

4. *Non-threshold Effects—carcinogenicity.* Using the Guidelines for Carcinogen Risk Assessment, Bayer believes FOE 5043 to be in Group E for carcinogenicity—no evidence of carcinogenicity—based on the results of carcinogenicity studies in three species. There was no evidence of carcinogenicity in an 18–month feeding study in mice, a 2–year feeding study in rats, or a 1–year feeding study in dogs at the dose levels tested. The doses tested are adequate for identifying a cancer risk. Thus, a cancer risk assessment should not be necessary for FOE 5043.

5. *Aggregate Exposure.* For purposes of assessing the potential dietary exposure under the proposed tolerances for FOE 5043, the estimated aggregate exposure was based on the Theoretical Maximum Residue Concentrations (TMRC) and the proposed tolerances (The TMRC is a worst case estimate of dietary exposure since it is assumed that 100 % of all crops for which tolerances are established are treated and that pesticide residues are present at the tolerance levels.). Registration for FOE 5043 and AXIOM are currently being sought on field corn and soybeans. FOE 5043 and AXIOM are not registered for any uses. Tolerances are proposed (pesticide petition number 6F 4631) for FOE 5043 on the following Raw Agricultural Commodities (RAC); field corn grain (0.05 ppm), forage (0.4 ppm) and stover (fodder) (0.4 ppm), soybean seed (0.1 ppm), milk (0.01 ppm), meat (0.05 ppm), and meat byproducts (0.05 ppm). The TMRC is obtained by multiplying the tolerance level for these commodities by consumption data which estimates the amounts of corn and soybean products eaten by various human population subgroups. Tolerances are proposed for milk, meat and meat byproducts because residues for FOE 5043 can be transferred from corn and soybean based feeds through livestock to humans.

This dietary exposure estimate assumes that 100% of these crops are treated with FOE 5043 and that the residues of FOE 5043 found in these crops would occur at the proposed tolerance levels. These assumptions result in an overestimate of exposure. In making a safety determination for these tolerances this conservative exposure estimate has been taken into account.

Other potential sources of exposure of the general population to residues of FOE 5043 are residues in drinking water and exposure from non-occupational sources. In ongoing ground water monitoring studies, trace levels of FOE 5043 residues (less that 1 part per billion (ppb) total residues) have been detected in ground water. These studies are being performed at sites with vulnerable shallow aquifers and large amounts of irrigation are being applied monthly. The highest residue level detected is well below the anticipated life-time Health Advisory Level of 84 ppb. If residues of FOE 5043 do occur in ground water used for drinking water they will be far below the level which causes concern. Based on the available data, no significant residues of FOE 5043 are anticipated to occur in surface water used for drinking water. Since registration is not being sought for any residential or homeowner uses no other potential for exposure to FOE 5043 residues exists.

The toxicological profile for FOE 5043 is fundamentally characterized by structural- and functional-related alterations in thyroid, hematologic and hepatic parameters. These sort of changes are not uncommon among herbicides. Since residues of FOE 5043 and its degradates will occur in raw agricultural commodities and processed foods in the high parts per billion or low parts per million range there is no compelling evidence that suggests a cumulative effect (i.e., potentiated, additive, or synergistic response) might occur or be anticipated in the human following exposure to multiple chemical agents with similar toxicological profiles and/or mechanisms of toxicity.

6. *Determination of safety for U.S. population—Reference dose (RfD).* Using the conservative exposure assumptions described above, based on the completeness and reliability of the toxicity data, the aggregate exposure to FOE 5043 will utilize 2.1% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100 % of the RfD. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Bayer concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of FOE 5043, including all anticipated dietary exposure and all other non-occupational exposures.

7. *Determination of Safety for Infants and Children.* The possibility of FOE 5043 induced developmental toxicity was suggested in preliminary and non-definitive toxicity studies using rats (> 175 mg/kg bwt/day) and rabbits (> 125 mg/kg bwt/day). However NOAELs for developmental effects were ultimately established in the definitive studies. Those values, as mentioned previously, were 25 mg/kg bwt/day in the rat and 25 mg/kg bwt/day in the rabbit.

Reference Dose (RfD). Using the conservative exposure assumptions described previously, Bayer has concluded that the percent of the RfD utilized by aggregate exposure to residues of FOE 5043 ranges from 1.1 % for non-nursing infants, up to 5.2 % for children 1 to 6 years old. EPA generally has no concern for exposure below 100 % of the Reference Dose. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Bayer concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the residues of FOE 5043, including all anticipated dietary exposure and all other non-occupational exposures.

8. *Estrogenic Effects.* No specific tests have been conducted with FOE 5043 to determine whether the pesticide may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

9. *Chemical Residue.* The qualitative nature of the residues in plants and animals is adequately understood for the purposes of registration. Residues of FOE 5043 do concentrate slightly (1.6x) in the processed commodity of corn grits. No tolerance has been proposed for residue of FOE 5043 in corn grits because anticipated residues are less than two times the limit of quantitation for the analytical method. There are no Codex maximum residue levels established for residues of FOE 5043 on any crop. Bayer has submitted a practical analytical method for detecting and measuring levels of FOE 5043 in or on food with a limit of detection that allows monitoring of food with residues at or above the proposed tolerance levels. EPA will provide information on

this method to FDA. The method is available to anyone who is interested in pesticide residue enforcement from the EPA's Field Operations Division, Office of Pesticide Programs.

Fifty-five separate residue trials have been conducted with FOE 5043 on corn and soybeans. Analysis of these trials shows that the maximum total combined residue for FOE 5043 and its major metabolites in any commodity will be at/below 9.75 ppm. Residues occurred at this level in soybean dry hay. However, no tolerances have been proposed for residues of FOE 5043 on soybean hay because the proposed labels for products containing FOE 5043 do not allow livestock to be fed with FOE 5043 treated soybean hay.

Tolerances have been requested for residues of FOE 5043 and its major metabolites on field corn grain (0.05 ppm), forage (0.4 ppm) and stover (fodder) (0.4 ppm) and soybean seed (0.1 ppm), milk (0.01 ppm), meat (0.05 ppm), and meat byproducts (0.05 ppm).

The proposed tolerance levels are adequate to cover residues likely to be present from the proposed use of FOE 5043. Therefore, no special processing to reduce the residues will be necessary.

There is no need for tolerances in poultry or eggs since there is no reasonable expectation of residues in these materials based on the results of poultry metabolism studies, as well as the corn and soybean metabolism and rotational crop studies. Calculated transfer factors are extremely low and maximum expected residues in poultry and eggs would be in the low parts per billion or high parts per trillion range. The anticipated residues in poultry tissues and eggs resulting from feeding poultry FOE 5043 treated corn and or soybeans would be far below the limit of quantitation of the analytical residue method.

No FOE 5043 food additive tolerances are proposed for field corn starch (wet milling), field corn refined oil (wet milling), field corn flour (dry milling) and field corn refined oil (dry milling) because no residues were detected above the limit of quantitation in this processed commodity.

Additionally, no FOE 5043 food additive tolerances are proposed in field corn grits (dry milling) field corn meal (dry milling), soybean meal, soybean hulls, and soybean refined oil because the measured concentration, when adjusted for the exaggerated application rate, was less that two times the limit of quantitation.

No feed additive tolerances are proposed for FOE 5043 in the aspirated grain fractions of corn and soybeans. With pre-plant and or pre-emergent modes of application for AXIOM DF and FOE 5043 DF, no residues were expected on the seed surface in the corn and soybean magnitude of residue studies. Therefore, no aspirated grain fractions were collected for analysis. A tolerance has not been proposed for soybean forage because feeding soybean hay and forage (silage) to livestock animals is not permitted by the proposed label.

Also, no feed additive tolerances are proposed for soybean meal or hulls since the measured concentration in the soybean processing study for these feeds, when adjusted for the exaggerated application rate, was less that two times the limit of quantitation.

No tolerances are proposed for corn milled by-products. Table II (September 1995) advises use residue data for corn dry-milled processed commodities having the highest residues, excluding oils. No residues were detected in the dry-milled processed commodities above the limit of quantitation.

10. *Environmental Fate.* Laboratory studies indicate that FOE 5043 residue has the potential to be moderately mobile in soil. However the results of field dissipation studies performed in Wisconsin and North Carolina, both corn and/or soybean producing states, indicate that downward movement of FOE 5043 residue is limited, with no quantifiable residues being found below 18 inches. These studies were conducted under conditions conducive to downward movement of FOE 5043 and degradates (very high sand content, low organic matter, and large volumes of applied irrigation).

FOE 5043 has been found to be stable to chemical hydrolysis in the pH range of environmental concern. The compound is also stable in water and soil when exposed to artificial sunlight.

Microbial degradation is the principal means of dissipation in soil. Half-lives for aerobic microbial degradation range from 10 to 34 days in varying soil types at the anticipated field application rate. Degradation of FOE 5043 in soil under aerobic conditions occurs by cleavage of the thiadiazole ring to form 3-trifluoromethyl-1,3,4-thiadiazol-2(3H)one (FOE thiadone) and the corresponding alcohol, *N*-(4-flurophenyl)-2-hydroxy-*N*-(1-methylethyl)acetamide. The FOE thiadone is further metabolized to CO2, and the alcohol is subsequently oxidized to [4-flurophenyl)(1-methylethyl)amino]oxoacetic acid. Another major degradation product of FOE 5043 is 4-fluoro-*N*-methylethylaniline-sulfoacetamide which is proposed to form through the oxidation of a cysteine conjugate intermediate. (PM 22)

PP 5F4577

EPA has received a pesticide petition (PP) 5F4577 from Bayer Corporation, 8400 Hawthorn Rd., P.O. Box 4913, Kansas City, MO 64120-0013 proposing, pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a, to amend 40 CFR 180.474 by establishing tolerances for residues of the fungicide tebuconazole in or on the raw agricultural commodities grass forage at 8.0 ppm and grass hay at 25.0 ppm and tolerances for residues of the fungicide tebuconazole in or on the raw agricultural commodities cattle liver at 0.2 ppm, cattle kidney at 0.2 ppm, cattle meat byproducts at 0.2 ppm, and milk at 0.1 ppm. The proposed analytical method for determining residues uses gas-liquid chromatography coupled with a thermionic detector. EPA has determined that the 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. (PM 21)

Tebuconazole is a sterol demethylation inhibitor (DMI) fungicide. It is systemic and shows activity against rusts (Puccinia spp.) and powdery mildew infecting grasses grown for seed. Tebuconazole provides protective activity by preventing completion of the infection process. It is rapidly absorbed by plants and is translocated systemically in the young growing tissues.

A. Residue Chemistry

1. *Plant and livestock metabolism.* Bayer believes the nature of the residue in plants and animals is adequately understood. The residue of concern is the parent compound only, as specified in 40 CFR 180.474.

2. *Analytical method.* Bayer has submitted an enforcement method for plant commodities has been validated on various commodities. It has undergone successful EPA validation and has been submitted for inclusion in PAM II. The method should be adequate for grasses grown for seed. The animal method has also been approved as an adequate enforcement method and will be submitted to FDA for inclusion in PAM II.

3. *Magnitude of residue.* Nine separate residue trials have been conducted and submitted to the EPA with tebuconazole on grasses grown for seed. The EPA has

determined that these data show that residues of tebuconazole,α-[2-(4-Chlorophenyl)ethyl]-α-(1,1-dimethylethyl)-*H*-1,2,4-triazole-1-eth anol, are not expected to exceed 8 ppm in grass forage and 25 ppm in grass hay as a result of the proposed use. In addition, the EPA has determined that tolerances are needed for the following animal commodities: cattle liver, kidney and meat byproducts at 0.2 ppm and milk at 0.1 ppm. The tolerance expression for the animal commodities will include the HWG 2061 metabolite,α-[2-(4-Chlorophenyl)-ethyl]-α-[(2-hydroxy-1,1-dimethyl)ethyl]-1*H*-1,2,4triazole-1-ethanol, in addition to the parent.

No processed commodities are associated with the proposed use on grasses grown for seed. In addition, due to the nature of the crop, rotational crops will not be an issue.

B. Toxicological Profile of Tebuconazole

1. *Acute toxicity.* i. Rat acute oral study with an LD_{50} of > 5,000 mg/kg (male) and 3,933 mg/kg (female)

ii. Rabbit acute dermal of LD_{50} of > 5,000 mg/kg

iii. Rat acute inhalation of LC_{50} of > 0.371 mg/l

iv. Primary eye irritation study in the rabbit which showed mild irritation reversible by day 7

v. Primary dermal irritation study which showed no skin irritation

vi. Primary dermal sensitization study which showed no sensitization

2. *Genotoxicity.* i. An Ames mutagenesis study in Salmonella showed no mutagenicity with or without metabolic activation.

ii. A micronucleus mutagenesis assay study in mice showed no genotoxicity.

iii. A sister chromatid exchange mutagenesis study using CHO cells was negative at dose levels 4 to 30 µg/mL without activation or 15 to 120 µg/mL with activation.

iv. An unscheduled DNA synthesis (UDS) study was negative for UDS in rat hepatocytes.

3. *Reproductive and developmental toxicity.* i. A rat oral developmental toxicity study with a maternal NOEL of 30 milligrams per kilogram of body weight per day (mg/kg bwtt/day) and an LEL of 60 mg/kg bwtt/day based on elevation of absolute and relative liver weights. For developmental toxicity, a NOEL of 30 mg/kg bwtt/day and an LEL of 60 mg/kg bwtt/day was determined, based on delayed ossification of thoracic, cervical and sacral vertebrae, sternum, fore and hind limbs and increase in supernumerary ribs.

ii. A rabbit oral developmental toxicity study with a maternal NOEL of 30 mg/kg bwt/day and an LEL of 100 mg/kg bwt/day based on depression of body weight gains and food consumption. A developmental NOEL of 30 mg/kg bwt/day and an LEL of 100 mg/kg bwt/day were based on increased post-implantation losses, from both early and late resorptions and frank malformations in eight fetuses of five litters.

iii. A mouse oral developmental toxicity study with a maternal NOEL of 10 mg/kg bwt/day and an LEL of 20 mg/kg bwt/day based on a supplementary study indicating reduction in hematocrit and histological changes in liver. A developmental NOEL of 10 mg/kg bwt/day and an LEL of 30 mg/kg bwt/day based on dose-dependent increases in runts/dam at 30 and 100 mg/kg bwt/day.

iv. A mouse dermal developmental toxicity study with a maternal NOEL of 30 mg/kg bwt/day and an LEL of 60 mg/kg bwt/day based on a supplementary study indicating increased liver microsomal enzymes and histological changes in liver. The NOEL for developmental toxicity in the dermal study in the mouse is 1,000 mg/kg bwt/day, the highest dose tested (HDT).

v. A two-generation rat reproduction study with a dietary maternal NOEL of 15 mg/kg bwt/day (300 ppm) and an LEL of 50 mg/kg bwt/day (1,000 ppm) based on depressed body weights, increased spleen hemosiderosis, and decreased liver and kidney weights. A reproductive NOEL of 15 mg/kg bwt/day (300 ppm) and an LEL of 50 mg/kg bwt/day (1,000 ppm) were based on neonatal birth weight depression.

4. *Subchronic toxicity.* i. 28-day feeding study in the rat with a NOEL of 30 mg/kg/day and a LEL of 100 mg/kg/day based on changes in hematology and clinical chemistry parameters.

ii. A 90–day rat feeding study with a no-observed-effect level (NOEL) of 34.8 (mg/kg bwt/day) (400 ppm) and a lowest-effect-level (LEL) of 171.7 mg/kg bwt/day (1,600 ppm) in males, based on decreased body weight gains and histological changes in the adrenals. For females, the NOEL was 10.8 mg/kg bwt/day (100 ppm) and the LEL was 46.5 mg/kg bwt/day (400 ppm) based on decreased body weights, decreased body weight gains, and histological changes in the adrenals.

iii. A 90–day dog-feeding study with a NOEL of 200 ppm (73.7 mg/kg bwt/day in males and 73.4 mg/kg bwt/day in females) and an LEL of 1,000 ppm (368.3 mg/kg bwt/day in males and 351.8 mg/kg bwt/day in females). The LEL was based on decreases in mean body weights, body weight gains, and food consumption, and an increase in liver *N*-demethylase activity.

5. *Chronic toxicity* i. A 2–year rat chronic feeding study defined a NOEL of 7.4 mg/kg bwt/day (100 ppm) and an LEL of 22.8 mg/kg bwt/day (300 ppm) based on body weight depression, decreased hemoglobin, hematocrit, MCV and MCHC, and increased liver microsomal enzymes in females. Tebuconazole was not oncogenic at the dose levels tested (0, 100, 300, and 1,000 ppm).

ii. A 1–year dog feeding study with a NOEL of 1 mg/kg bwt/day (40 ppm) and an LEL of 5 mg/kg bwt/day (200 ppm), based on lenticular and corneal opacity and hepatic toxicity in either sex (the current Reference Dose was determined based on this study). A subsequent 1–year dog feeding study, using lower doses to further define the NOEL for tebuconazole, defines a systemic LOEL of 150 ppm (based on adrenal effects in both sexes) and a systemic NOEL of 100 ppm.

iii. A mouse oncogenicity study at dietary levels of 0, 20, 60, and 80 ppm for 21 months did not reveal any oncogenic effect for tebuconazole at any dose tested. Because the maximum-tolerated-dose (MTD) was not reached in this study, the study was classified as supplementary. A follow-up mouse study at higher doses (0, 500, and 1,500 ppm in the diet), with an MTD at 500 ppm, revealed statistically significant incidences of hepatocellular adenomas and carcinomas in males and carcinomas in females. The initial and follow-up studies, together with supplementary data were classified as core minimum.

6. *Animal metabolism.* A general rat metabolism study at dietary levels of 2 and 20 mg/kg showed rapid elimination from the rat in 3 days (some 99% excreted by the feces and urine and 0.0304% in expired air). Increased concentrations of radioactivity from the active ingredient and metabolites were found only in the liver. The bones and the brain were among the tissues showing the least amount of radioactivity.

7. *Metabolite toxicity.* The residue of concern in plants is the parent compound, tebuconazole, only. For animal commodities, the EPA has determined that the tolerance expression should include the HWG 2061 metabolite, α-[2-(4 -Chlorophenyl)-ethyl]-α-[(2-hydroxy-1,1-dimethyl)ethyl]-1*H*-1,2,4triazole-1-ethanol. An acute oral toxicity study has been submitted to the EPA on this metabolite. This study shows an oral LD50 of > 5,000 for female rats. This value indicates that the HWG 2061 metabolite is relatively innocuous and less acutely toxic than tebuconazole.

8. *Endocrine effects.* No special studies investigating potential estrogenic or endocrine effects of tebuconazole have been conducted. However, the standard battery of required studies has been completed. These studies include an evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following repeated or long-term exposure. These studies are generally considered to be sufficient to detect any endocrine effects but no such effects were noted in any of the studies with either tebuconazole or its metabolites.

9. *Carcinogenicity.* EPA's Carcinogenicity Peer Review Committee (CPRC) has classified tebuconazole as a Group C carcinogen (possible human carcinogen). This classification is based on the Agency's ''Guidelines for Carcinogen Risk Assessment'' published in the **Federal Register** of September 24, 1986 (51 FR 33992). The Agency has chosen to use the reference dose calculations to estimate human dietary risk from tebuconazole residues. The decision supporting classification of tebuconazole as a possible human carcinogen (Group C) was primarily based on the statistically significant increase in the incidence of hepatocellular adenomas, carcinomas, and combined adenomas/carcinomas in both sexes of NMRI mice both by positive trend and pairwise comparison at the highest dose tested.

C. Aggregate Exposure

1. *Dietary (food) exposure.* For purposes of assessing the potential dietary exposure from food under the proposed tolerances, Bayer has been advised that the EPA has estimated exposure based on the Theoretical Maximum Residue Contribution (TMRC) derived from the previously established tolerances for tebuconazole on cherries, peaches, bananas, barley, oats, wheat, and peanuts as well as the proposed tolerances for tebuconazole on milk at 0.1 ppm and cattle liver, kidney and meat byproducts at 0.2 ppm. The TMRC is obtained by using a model which multiplies the tolerance level residue for each commodity by consumption data which estimate the amount of each commodity and products derived from the commodities that are eaten by the U.S. population and various population subgroups. In conducting this exposure assessment, the EPA has made very conservative assumptions—100% of all commodities will contain tebuconazole residues, and those residues would be at the level of the tolerance—which result in a large overestimate of human exposure. Thus, in making a safety determination for these tolerances, the Agency took into account this very conservative exposure assessment.

2. *Dietary (drinking water) exposure.* There is no Maximum Contaminant Level established for residues of tebuconazole. Bayer was advised by the Environmental Fate and Ground Water Branch's (EFGWB) May 26, 1993 memorandum for our application for use on bananas and peanuts that all environmental fate data requirements for tebuconazole were satisfied. The EFGWB had determined that tebuconazole is resistant to most degradative processes in the environment, including hydrolysis, photolysis in water and aerobic and anaerobic metabolism. Only minor degradation occurred in soil photolysis studies. The photolytic half-life of tebuconazole is 19 days. Laboratory and field studies have shown that the mobility of tebuconazole in soil is minimal. Therefore, Bayer concludes that tebuconazole bears no apparent risk to ground water under most circumstances.

3. *Non-dietary exposure.* Although current registrations and the proposed use for grasses grown for seed are limited to commercial crop production, Bayer has submitted an application to register tebuconazole on turf. Bayer has conducted an exposure study designed to measure the upper bound acute exposure potential of adults and children from contact with tebuconazole treated turf. The population considered to have the greatest potential exposure from contact with pesticide treated turf soon after pesticides are applied are young children. Margins of exposure (MOE) of 1,518 8,561 for 10-year-old children and 1,364 - 7,527 for 5-year-old children were estimated by comparing dermal exposure doses to the tebuconazole no-observable effect level of 1,000 mg/kg/day established in a subacute dermal toxicity study in rabbits. The estimated safe residue levels for tebuconazole on treated turf for 10-year-old children ranged from 4.8 - 27.3 $\mu g/cm^2$ and for 5-year-old children from 4.4 - 24.0 $\mu g/cm^2$. This compares with the average tebuconazole transferable residue level of 0.319 $\mu g/cm^2$ present immediately after the sprays have dried. Bayer concludes that these data indicate that children can safely contact tebuconazole-treated turf as soon after application as the spray has dried.

D. Cumulative Effects

At this time, the EPA has not made a determination that tebuconazole and other substances that may have a common mechanism of toxicity would have cumulative effects. Therefore, for this tolerance, Bayer has considered only the potential risks of tebuconazole in its aggregate exposure.

E. Safety Determination

1. *U.S. population.* Chronic Dietary Exposure: Based on a complete and reliable toxicity database, the EPA has adopted an RfD value of 0.03 mg/kg/day. This RfD is based on a 1–year dog study with a NOEL of 2.96 mg/kg/day and an uncertainty factor of 100. Using the conservative exposure assumptions described above, Bayer has been advised that the EPA has concluded that aggregate dietary exposure to tebuconazole from the previously established and the proposed tolerances will utilize 5.1 % of the RfD for the U.S. population (48 states) and 30.7% of the RfD for the most highly exposed population subgroup (non-nursing infants, <1 year old). There is generally 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, Bayer concludes that there is a reasonable certainty that no harm will result from aggregate exposure to tebuconazole.

2. *Acute dietary exposure.* EPA recently proposed a tiered approach to estimate acute dietary exposure. The methods proposed by the EPA were reviewed and supported by the FIFRA Scientific Advisory Panel (SAP, 1995). EPA's Tier 1 method is based on the assumption that residue concentrations do not vary. The analysis assumes that all residues have the same magnitude, typically the highest field trial residue or tolerance value. This value is assumed for all points along the consumption distribution, resulting in a distribution of dietary exposure. Bayer has been advised that the EPA conducted an acute dietary analysis using the NOEL of 10 mg/kg/day for developmental toxicity in the mouse. The EPA has calculated a high end Margin of Exposure (MOE) value of 1,000 for the population subgroup of concern (females 13+). In addition, Bayer has calculated 95th percentile MOE for the following population groups: overall U.S. population (MOE = 2,528), infants (MOE = 711), children 1 to 6 years of age (MOE = 1,145) , females 13 years and older (MOE = 4,285), and males 13 years and older (MOE = 3,685). Therefore, since EPA considers values of 100 or more satisfactory, there is no concern from acute dietary exposure.

3. *Infants and children.* In assessing the potential for additional sensitivity of

infants and children to residues of tebuconazole, the data from developmental studies in both rat and rabbit and a two-generation reproduction study in the rat should be considered. The developmental toxicity studies evaluate any potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates any effects from exposure to the pesticide on the reproductive capability of mating animals through two generations, as well as any observed systemic toxicity. A developmental toxicity study in the rat, a developmental toxicity study in the rabbit, two developmental studies in the mouse and a 2-generation rat reproduction study have been conducted with tebuconazole. Maternal and developmental toxicity NOELs of 30 mg/kg/day were determined in the rat and rabbit studies. An oral mouse developmental toxicity study had maternal and developmental toxicity NOELs of 10 mg/kg/day while the mouse dermal developmental study had a maternal NOEL of 30 mg/kg/day and a developmental toxicity NOEL of 1,000 mg/kg/day. The parental and reproductive NOELs in the 2-generation rat reproduction study were determined to be 15 mg/kg/day (300 ppm). In all cases, the reproductive and developmental NOELs were greater than or equal to the parental NOELs. This indicates that tebuconazole does not pose any increased risk to infants or children. 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 effects and the completeness of the toxicity database. Based on current toxicological data requirements, the toxicology database for tebuconazole relative to pre- and post-natal effects is complete. Further for tebuconazole, the NOEL of 2.96 mg/kg/bwtt from the 1–year dog study, which was used to calculate the RfD, is already lower than the NOELs from the developmental studies in rats (30 mg/kg bwt/day) and rabbits (30 mg/kg bwt/day) by a factor of 10 times. Since a hundredfold uncertainty factor is already used to calculate the RfD, Bayer surmises that an additional uncertainty factor is not warranted and that the RfD at 0.03 mg/kg/bwtt/day is appropriate for assessing aggregate risk to infants and children. Using the conservative exposure assumptions, Bayer has concluded from the EPA's recent chronic dietary analysis that the percent of the RfD utilized by aggregate exposure to residues of tebuconazole ranges from 14.2% for children 1 to 6 years old up to 30.7% for non-nursing infants. EPA generally has no concern for exposure below 100 % of the RfD. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Bayer concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the residues of tebuconazole, including all anticipated dietary exposure and all other non-occupational exposures.

F. International Issues

No CODEX Maximum Residue Levels (MRLs) have been established for residues of tebuconazole on any crops at this time. Data have not been submitted to the Joint Meeting of the Food and Agriculture Organization Panel of Experts on Pesticide Residues in Food and the Environment and the World Health Organization Expert Group on Pesticide Residues (JMPR) to establish Codex MRLs for grasses grown for seed.

G. Mode of Action

Tebuconazole, the active ingredient of Folicur 3.6 F is a sterol demethylation inhibitor (DMI) fungicide. It is systemic and shows activity against rusts (*Puccinia spp.*) and powdery mildew infecting grasses grown for seed. Tebuconazole provides protective activity by preventing completion of the infection process by direct inhibition of sterol synthesis. It is rapidly absorbed by plants and translocated systemically in the young growing tissues.

2. Ciba Crop Protection

6F4656/6H5746

EPA has received pesticide petitions (PP) 6F4656/6H5746 from Ciba Crop Protection, Ciba-Geigy Corporation, P.O. Box 18300, Greensboro, NC 27419, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C 346a, to amend 40 CFR part 180 by establishing tolerances for residues of the fungicide cyprodinil (4-cyclopropyl-6-methyl-*N*-phenyl-2-pyrimidinamine) in or on the agricultural commodities almond nutmeats at 0.04 ppm, almond hulls at 0.1 ppm, grapes at 3.0 ppm, raisins at 3.0 ppm, the pomefruit crop grouping at 0.1 ppm, apple pomace - wet at 0.4 ppm, and the stone fruit crop grouping at 2.0 ppm. The proposed analytical method for determining residues uses high performance liquid chromatography with UV detection. EPA has determined that the 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. (PM 21)

A. Cyprodinil Uses

Cyprodinil is the first fungicide in a new chemical class known as the anilinopyrimidine and is active against important Botrytis, Monilinia and Venturia diseases of deciduous fruit and nut crops. Cyprodinil with a unique mode of action, controls pathogens resistant to other chemical classes. Application rates range from 0.125 to 0.5 lb active ingredient per acre per application depending upon disease and time of application.

B. Residue Chemistry

1. *Metabolism*. Ciba believes the metabolism of cyprodinil has been well characterized in plants and animals. The metabolism profile supports the use of an analytical enforcement method that accounts for only parent cyprodinil.

2. *Analytical methodology.* Ciba has submitted a practical analytical method involving extraction, filtration, and solid phase cleanup of samples with analysis by HPLC and UV. The limits of quantitation (LOQ) for various commodities are as follows: fruit, grain, juice - 0.02 ppm; forage, fodder, straw - 0.05 ppm; and grapes - 0.01 ppm.

C. Magnitude of Residue

This petition is supported by field residue trials conducted on almonds, grapes, and representative members of the Pome Fruit and the Stone Fruit Crop Groupings. All samples were analyzed for parent residues of cyprodinil.

Residues found in the almond nutmeats and hulls were all less than respective LOQ's of 0.02 ppm and 0.05 ppm. Tolerances at twice the LOQ for these commodities have been proposed. In grapes, the maximum residues found for fresh fruit and raisins were 2.0 ppm and 2.9 ppm, respectively. Residues did not concentrate in grape juice. Tolerances of 3.0 ppm for grapes and raisins have been requested. In pome fruit, maximum residues ranged from 0.030 ppm to 0.061 ppm. The results of a processing study on apples using exaggerated rates showed concentration of residues in wet pomace with an average concentration factor of 4X. Residues in apple juice were not detectable at the LOQ (< 0.01 ppm). Tolerances of 0.1 ppm for the RAC of the Pome Fruit Crop Grouping and 0.4 ppm for wet apple pomace have been proposed. In stone fruit, maximum

residues ranged from 0.82 ppm to 1.7 ppm. A tolerance of 2.0 ppm has been proposed for the Stone Fruit Crop Grouping. Based upon the results of a three level dairy feeding study, Ciba believes no transfer of residue to animals is expected through their diet and that tolerances in milk, meat, poultry, and eggs are not required.

D. International Tolerances

There are no Codex Alimentarius Commission (CODEX) maximum residue levels (MRL's) established for residues of cyprodinil in or on raw agricultural commodities.

E. Toxicological Profile of Cyprodinil

The following mammilian toxicity studies have been conducted to support the tolerances of cyprodinil:

1. A rat acute oral study for cyprodinil with a LD_{50} of 2,796 mg/kg.
2. A rat acute dermal study for cyprodinil with a LD_{50} > 2,000 mg/kg.
3. A rat inhalation study for cyprodinil with a LC_{50} > 1.2 mg/liter air.
4. A primary eye irritation study in rabbits showing cyprodinil as minimally irritating.
5. A primary dermal irritation study in rabbits showing cyprodinil as slightly irritating.
6. A skin sensitization study in guinea pigs showing cyprodinil as a weak sensitizer.
7. A 28–day dermal study in the rat with a NOEL of 5 mg/kg based on clinical signs.
8. A 90–day feeding study in the dog with a NOEL of 1500 ppm (37.5 mg/kg) based on reduced food intake and body weight.
9. A 90–day feeding study in the mouse with a NOEL of 500 ppm (75 mg/kg) based on liver histologic changes.
10. A 90–day feeding study in the rat with a NOEL of 50 ppm (5 mg/kg) based on hematologic and histologic findings.
11. A 12–month feeding study in the dog with a NOEL of 2,500 ppm (62.5 mg/kg) based on liver histologic changes.
12. An 18–month oncogenicity feeding study in the mouse with a NOEL of 2,000 ppm (300 mg/kg). The MTD was 5,000 ppm based on reduction in body weight gain and no evidence of oncogenicity was seen.
13. A 24–month chronic feeding/oncogenicity study in the rat with a NOEL of 75 ppm (3.75 mg/kg) based on hematologic and histologic findings. The MTD was 2,000 ppm based on liver histopathology and no evidence of oncogenicity was seen.
14. An oral teratology study in the rat with a maternal NOEL of 200 mg/kg based on reductions in body weight gain and food consumption and a fetal NOEL of 200 mg/kg based on decreased pup weight and delayed skeletal growth at 1,000 mg/kg.
15. An oral teratology study in the rabbit with a maternal NOEL of 150 mg/kg based on reduction in body weight gain and a fetal NOEL of 400 mg/kg based on the absence of any fetal effects.
16. A 2–generation reproduction study in the rat with a systemic NOEL of 100 ppm and a fetal NOEL of 1,000 ppm (100 mg/kg). A slight decrease in pup weight at birth and subsequent body weight gain during the lactation phase was observed only at the maternally toxic dose of 4,000 ppm without any effects on reproduction and fertility.
17. *In vitro* gene mutation test: Ames assay - negative; Chinese hamster V79 cell test - negative; rat hepatocyte DNA repair test - negative.
18. *In vitro* chromosome test: Chinese hamster ovary cell cytogenetic test - negative.
19. *In vivo* mutagenicity test: mouse bone marrow test - negative.

F. Threshold Effects

1. *Chronic effects*. Based on the available chronic toxicity data, Ciba Crop Protection believes the Reference dose (RfD) for cyprodinil is 0.0375 mg/kg/day. This RfD is based on a 2–year feeding study in rats with aNo-Observed Effect Level (NOEL) of 3.75 mg/kg/day (75 ppm) and an uncertainly factor of 100. No additional modifying factor for the nature of effects was judged to be necessary as liver sinusoidal dilatation was the most sensitive indicator of toxicity in that study.

2. *Acute toxicity.* The risk from acute dietary exposure to cyprodinil is considered to be very low. The lowest NOEL in a short term exposure scenario, identified as 150 mg/kg in the rabbit teratology study, is fortyfold higher than the chronic NOEL. Since chronic exposure assessment did not result in any margin of exposure less than 400 for even the most impacted population subgroup, Ciba believes the margin of exposure is greater than 100 for any population subgroups; EPA considers margins of exposure of 100 or more as satisfactory.

G. Non-threshold Effects

Using the Guidelines for Carcinogenic Risk Assessment published September 24, 1986 (51 FR 33992), Ciba believes cyprodinil to be in Group ''E''(no evidence of carcinogenicity. There was no evidence of carcinogenicity in an 18–month feed study in mice and a 24–month feeding in rats. Dosage levels in both the mouse and the rat studies were adequate for identifying a cancer risk.

H. Aggregate Exposure

1. *Dietary exposure.* For the purposes of assessing the potential dietary exposure under the proposed tolerances, Ciba has estimated aggregate exposure based upon the Theoretical Maximum Residue Concentration (TMRC) from the requested tolerances: Almonds — 0.04 ppm for the raw agricultural commodity (RAC) and 0.1 ppm for hulls; Grapes — 3.0 ppm for the RAC and 3.0 ppm for raisins; Pome Fruit Crop Grouping — 0.1 ppm for the RAC and 0.4 ppm for apple wet pomace; and Stone Fruit Crop Grouping — 2.0 ppm for the RAC. The TMRC is a ''worst case'' estimate of dietary exposure since it assumes 100 % of all crops for which tolerances are established are treated and that pesticide residues are at the tolerance levels. In conducting this exposure assessment, Ciba has made very conservative assumptions — 100% of all almonds, grapes, pome fruit and stone fruit commodities will contain cyprodinil residues at tolerance levels — which result in an overestimate of human exposure.

2. *Drinking water exposure.* Cyprodinil is rapidly degraded in the environment via photolysis and microbial degradation; aqueous and soil photolysis half lives for cyprodinil are 12 days and 67 days, respectively. The aerobic metabolism half life is 25 days and the leaching potential for cyprodinil is low (K_{oc} = 1,550 to 2,030). Based on these data, Ciba does not anticipate exposure to residue of cyprodinil in drinking water.

3. *Non-dietary exposure.* Ciba believes that the potential for non-occupational exposure to the general public is unlikely except for potential residues in food crops discussed above. The proposed uses for cyprodinil are for agricultural crops and the product is not used residentially in or around the home.

Ciba believes that consideration of a common mechanism of toxicity is not appropriate at this time since there is no information to indicate that toxic effects produced by cyprodinil would be cumulative with those of any other chemicals. Consequently, Ciba is considering only the potential exposure to cyprodinil in its aggregate risk assessment.

I. Safety To the U.S. Population

Reference dose. Using the conservative exposure assumptions described above and based on the completeness and reliability of the toxicity data base for cyprodinil, Ciba

has calculated aggregate exposure levels for this chemical. Based on chronic toxicity endpoints, only 4% of the RfD will be utilized for the U.S. general population. EPA usually 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. Ciba concludes that there is a reasonable certainty that no harm will result from aggregate exposure to cyprodinil residues.

J. Safety to Infants and Children

Developmental delays (reduced pup weight and ossification) were observed in the rat teratology study and 2-generation rat reproduction study at maternally toxic doses. The lowest NOEL for this effect was established in the 2-generation study at 100 mg/kg (1,000 ppm). The finding is judged to be a nonspecific, secondary effect of maternal toxicity. No developmental toxicity was observed in the rabbit teratology study.

Reference dose. Using the same conservative exposure assumptions as employed for the determination in the general population, Ciba has calculated the utilization of RfD by aggregate exposure to residues of cyprodinil to be 12% for nursing infants less than 1 year old, 22% for non-nursing infants less than 1 year old, 12% for children 1 to 6 years old, and 6% for children 7 to 12 years old. Ciba believes that under the worst case assumptions which overestimate exposure to infants and children, there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to cyprodinil residues.

K. Estrogenic effects

Cyprodinil does not belong to a class of chemicals known or suspected of having adverse effects on the endocrine system. Developmental toxicity studies in rats and rabbits and a reproduction study in rats gave no indication that cyprodinil might have any effects on endocrine function related to development and reproduction. The chronic studies also showed no evidence of a long-term effect related to the endocrine system.

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[OPP–181041; FRL 5597–8]

Cymoxanil, Propamocarb Hydrochloride and Dimethomorph; Receipt of Applications for Emergency Exemptions, Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received specific exemption requests from the Florida Department of Agriculture and Consumer Services (hereafter referred to as the ''Applicant'') to use the pesticides cymoxanil (CAS 57966–95–7), propamocarb hydrochloride (CAS 25606–41–1) and dimethomorph (CAS 110488–70–5) to treat potentially up to 50,000 acres of tomatoes to control immigrant strains of late blight which are resistant to historically used control materials. The Applicant proposes the use of either new (unregistered) chemicals or the first food use of an active ingredient therefore, in accordance with 40 CFR 166.24, EPA is soliciting public comment before making the decision whether or not to grant the exemptions.

DATES: Comments must be received on or before April 17, 1997.

ADDRESSES: Three copies of written comments, bearing the identification notation ''OPP–181041,'' should be submitted by mail to: Public Response and Program Resource Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under ''SUPPLEMENTARY INFORMATION'' of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted in any comment concerning this notice may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be provided by the submitter for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments filed pursuant to this notice will be available for public inspection in Rm. 1132, Crystal Mall No. 2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Libby Pemberton, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail: Floor 6, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA, (703) 308–8326; e-mail: pemberton.libby@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Pursuant to section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), the Administrator may, at her discretion, exempt a state agency from any registration provision of FIFRA if she determines that emergency conditions exist which require such exemption. The Applicant has requested the Administrator to issue specific exemptions for the use of cymoxanil, propamocarb hydrochloride, and/or dimethomorph on tomatoes to control late blight. Information in accordance with 40 CFR part 166 was submitted as part of this request.

Recent failures to control late blight in tomatoes as well as potatoes with the registered fungicides, have been caused almost exclusively by immigrant strains of late blight *Phytophthora infestans*, which are resistant to the control of choice, metalaxyl. Before the immigrant strains of late blight arrived, all of the strains in the U.S. were previously controlled by treatment with metalaxyl.

The Applicant states that presently, there are no fungicides registered in the U.S. that will provide adequate control of the immigrant strains of late blight. The Applicant states that each of these requested chemicals has been shown to be effective against these strains of late blight. Each active ingredient holds current registrations throughout many European countries for control of this disease. The Applicant indicates that at least a 30 percent yield reduction is expected based on the current infestation. Net revenues are expected to be reduced by over $12 million for the affected acreage without the use of these requested chemicals.

The Applicant proposes to apply propamocarb hydrochloride, manufactured by AgrEvo USA Company, as Tattoo C, at a maximum rate of 0.9 lbs. active ingredient [(a.i.)], (2.3 pt of product) per acre by ground or air, with a maximum of 5 applications per season. A 7–day PHI will be observed. Use under this exemption could potentially amount to