Branch (PIRIB), Rm. 119, Crystal Mall 2 (CM 2), 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–30489 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, CM 2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: ''opp-docket@epa.gov,'' or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP–30489. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under ''FOR FURTHER INFORMATION CONTACT.''

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the registration activity.

7. Make sure to submit your comments by the deadline in this notice.

8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Registration Application

EPA received application as follows to register pesticide product containing active ingredient not included in any previously registered product pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of this application does not imply a decision by the Agency on the application.

Product Containing Active Ingredient not Included in any Previously Registered Product

File Symbol: 69876–R: *Applicant:* Camas Technologies, Inc., PO Box 1357, Broomfield, Colorado 80038–1357. *Product name:* QWEL Fungicide. *Active Ingredient:* Macleaya Extract. *Proposed Classification/Use:* None. For foliar control of fungi on greenhouse ornamentals. *Type registration:* Conditional.

List of Subjects

Environmental protection, Pesticides and pest.

Dated: January 5, 2000

James Jones,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 00–1217 Filed 1–18–00; 8:45 am

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–912; FRL–6485–8]

Notice of Filing a Pesticide Petition to Establish a Tolerance for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket control number PF–912, must be received on or before February 18, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–912 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–7740; e-mail address: giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing

Categories	NAICS	Examples of potentially affected entities
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under ''FOR FURTHER INFORMATION CONTACT.''

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**--Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–912. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall 2 (CM 2), 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

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1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, CM 2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: *''opp-docket@epa.gov*,'' or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–912. Electronic comments may also be filed online at many Federal Depository Libraries.

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1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of 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.

List of Subjects

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

Dated: January 11, 2000

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petition

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

EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. Novartis Crop Protection, Inc.

PP 9F05070

EPA has received a pesticide petition (PP 9F05070) from Novartis Crop Protection, Inc., PO 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(d), to amend 40 CFR part 180 by establishing a tolerance for residues of Trifloxystrobin in or on the raw agricultural commodities almond nutmeats at 0.02 parts per million (ppm), almond hulls at 1.5 ppm, fruiting vegetables crop group at 0.7 ppm, hops - dried cones at 11 ppm, potato tubers at 0.02 ppm, sugarbeet roots at 0.05 ppm, sugarbeet tops at 2.5 ppm, sugarbeet dried pulp at 0.25 ppm, wheat grain at 0.05 ppm, wheat forage at 0.03 ppm, wheat hay at 0.2 ppm, wheat straw at 0.05 ppm, and wheat aspirated grain fractions at 0.5 ppm. 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 trifloxystrobin in plants (cucumbers, apples, wheat and peanuts) is well understood. Identified metabolic pathways are substantially similar in plants and animals (goat, rat and hen). Novartis proposes trifloxystrobin, per se, as the residue of concern for tolerance setting purposes.

2. *Analytical method*. Novartis Crop Protection Inc. has submitted practical analytical methodology for detecting and measuring levels of trifloxystrobin in or on raw agricultural commodities. The limit of detection (LOD) for each analyte of this method is 0.08 ng injected, and the limit of quantitation (LOQ) is 0.02 ppm. The method is based on crop specific cleanup procedures and determination by gas chromatography with nitrogen-phosphorus detection.

3. *Magnitude of residues — residue trials*. A residue program was performed for trifloxystrobin on a full geography of tomatoes and peppers as representative fruiting vegetable crops, potatoes as a representative crop of tuberous and corm vegetables, almonds, hops, wheat, and sugarbeets. A study was conducted on indicator crops to assay for secondary residues in rotational crops. Novartis also completed a three-level poultry study to determine the rate of transfer of residues of trifloxystrobin from residues in animal feed to poultry commodities.

i. *Acute toxicity*. Studies conducted with the technical material of trifloxystrobin:

- Rat acute oral toxicity study with a LD_{50} >5,000 mg/kg
- Mouse acute oral toxicity study with a LD_{50} >5,000 mg/kg
- Rabbit acute dermal toxicity study with a LD_{50} >2,000 mg/kg
- Rat acute dermal toxicity study with a LD_{50} >2,000 mg/kg
- Rat acute inhalation toxicity study with a LC_{50} >4.65 mg/L
- Rabbit eye irritation study showing slight irritation (Category III)
- Rabbit dermal irritation study showing slight irritation (Category IV)
- Guinea pig dermal sensitization study with the Buehler's method showing negative findings
- Guinea pig clem sal sensitization study with the Maximization method showing some positive findings

ii. *Genotoxicty*. No genotoxic activity is expected of trifloxystrobin under *in-vivo* or physiological conditions. The compound has been tested for its potential to induce gene mutation and chromosomal changes in five different test systems. The only positive finding was seen in the *in vitro* test system (Chinese hamster V79 cells) as a slight increase in mutant frequency at a very narrow range (250 – 278 µg/ml) of cytotoxic and precipitating concentrations (compound solubility in water was reported to be 0.61 µg/ml; precipitate was visually noted in culture medium at 150 µg/ml). The chemical was found to be non-mutagenic in the *in vivo* system or all other *in vitro* systems. Consequently, the limited gene mutation activity in the V79 cell line is considered a nonspecific effect under non-physiological *in vitro* conditions and not indicative of a real mutagenic hazard.

iii. *Reproductive and developmental toxicity*. FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database on trifloxystrobin relative to pre- and post-natal effects for children is complete.

In assessing the potential for additional sensitivity of infants and children to residues of trifloxystrobin, Novartis considered data from teratogenicity studies in the rat and the rabbit and a 2–generation reproduction study in the rat. The teratogenicity studies are designed to evaluate adverse effects on the developing embryo as a result of chemical exposure during the period of organogenesis. Reproduction studies provide information on effects from chemical exposure on the reproductive capability of mating animals and systemic and developmental toxicity from *in utero* exposure.

In the rat teratology study, reductions in body weight gain and food consumption were observed in the dam at ≥ 100 mg/kg. No teratoganic effects or any other effects were seen on pregnancy or fetal parameters except for the increased incidence of enlarged thymus, which is a type of variation, at 1,000 mg/kg. The developmental no observed-adverse-effect level (NOAEL) was 100 mg/kg.

In the rabbit teratology study, body weight loss and dramatically reduced food consumption were observed in the dam at ≥ 250 mg/kg. No teratogenic effects or any other effects were seen on pregnancy or fetal parameters except for the increase in skeletal anomaly of fused sternebrae-3 and -4 at the top dose level of 500 mg/kg. This finding is regarded as a marginal effect on skeletal development that could have resulted from the 40- to 65% lower food intake during treatment at this dose level. The developmental NOAEL was 250 mg/kg.

In the 2–generation rat reproduction study, body weight gain and food consumption were decreased at > 750 ppm, especially in females during lactation. Consequently, the reduced pup weight gain during lactation (> 750 ppm) and the slight delay in eye opening (1,500 ppm) are judged to be a secondary effect of maternal toxicity. No other fetal effects or any reproductive changes were noted. The low developmental NOAEL, 50 ppm (5 mg/kg), seen in this study was probably due to the lack of intermediate dose levels between 50 and 750 ppm. Based on an evaluation of the dose-response relationship for pup weight at 750 ppm and 1,500 ppm, the NOAEL should have been nearly ten-fold higher if such a dose was available.

Based on all these teratology and reproduction studies, the lowest NOAEL for developmental toxicity is 5 mg/kg while the lowest NOAEL in the subchronic and chronic studies is 2.5

mg/kg/day (from the rat chronic study). Therefore, no additional sensitivity for infants and children to trifloxystrobin is suggested by the data base.

iv. *Subchronic toxicity*. In subchronic studies, several mortality related changes were reported for the top dose in dogs (500 mg/kg) and rats (800 mg/kg). At these dose levels, excessive toxicity has resulted in body weight loss and mortality with the associated and nonspecific changes in several organs (such as atrophy in the thymus, pancreas, bone marrow, lymph node, and spleen) which are not considered specific target organs for the test compound. In the dog, specific effects were limited to hepatocellular hypertrophy at 150 mg/kg and hyperplasia of the epithelium of the gall bladder at 500 mg/kg. Target organ effects in the rat were noted as hepatocellular hypertrophy (≥ 200 mg/kg) and the related liver weight increase (≥ 50 mg/kg). In the mouse, target organ effects included single cell necrosis (300 mg/kg) and hypertrophy (1,050 mg/kg) in the liver and extramedullary hematopoiesis (≥ 300 mg/kg) and hemosiderosis in the spleen (1,050 mg/kg).

In general, definitive target organ toxicity, mostly in the liver, was seen at high feeding levels of over 100 mg/kg for an extended treatment period. At the lowest observed adverse effect level, no serious toxicity was observed other than mostly non-specific effects including a reduction in body weight and food consumption or liver hypertrophy.

5. *Chronic toxicity*. The liver appears to be the major primary target organ based on the chronic studies conducted in mice, rats, and dogs. It was identified as a target organ in both the mouse and the dog studies with trifloxystrobin. However, no liver effect was seen in the chronic rat study which produced the lowest NOAEL of 2.5 mg/kg based on reduced body weight gain and food consumption seen at higher dose levels.

The compound did not cause any treatment-related increase in general tumor incidence, any elevated incidence of rare tumors, or shortened time to the development of palpable or rapidly lethal tumors in the 18–month mouse and the 24–month rat studies. Dosages in both studies were sufficient for identifying a cancer risk. In the absence of carcinogenicity, Novartis believes that a Reference Dose (RfD) approach is appropriate for quantitation of human risks.

6. *Animal metabolism*. Trifloxystrobin is moderately absorbed from the gastrointestinal tract of rats and is rapidly distributed. Subsequent to a single oral dose, the half life of elimination is about 2 days and excretion is primarily via bile. Trifloxystrobin is extensively metabolized by the rat into about 35 metabolites, but the primary actions are on the methyl ester (hydrolysis into an acid), the methoxyimino group (*O*-demethylation), and the methyl side chain (oxidation to a primary alcohol). Metabolism is dose dependent as it was almost complete at low doses but only about 60% complete at high doses.

In the goat, elimination of orally administered trifloxystrobin is primarily via the feces. The major residues were the parent compound and the acid metabolite (CGA–321113) plus its conjugates. In the hen, trifloxystrobin is found as the major compound in tissues and in the excreta, but hydroxylation of the trifluormethyl-phenyl moiety and other transformations, including methyl ester hydrolysis and demethylation of the methoxyimino group, are also seen. In conclusion, the major pathways of metabolism in the rat, goat, and hen are the same.

7. *Metabolite toxicology*. Metabolism of trifloxystrobin has been well characterized in plants, soil, and animals. In plants and soil, photolytically induced isomerization results in a few minor metabolites not seen in the rat; however, most of the applied materials remained as parent compound as shown in the apple and cucumber studies. All quantitatively major plant and/or soil metabolites were also seen in the rat. The toxicity of the major acid metabolite, CGA–321113 (formed by hydrolysis of the methyl ester), has been evaluated in cultured rat hepatocytes and found to be 20-times less cytotoxic than the parent compound. Additional toxicity studies were conducted for several minor metabolites seen uniquely in plants and/or soil. The studies indicate that these metabolites, including CGA–357261, CGA–373466, and NOA–414412, are not mutagenic to bacteria and are of low acute toxicity (LD_{50} > 2,000 mg/kg). In conclusion, the metabolism and toxicity profiles support the use of an analytical enforcement method that accounts for parent trifloxystrobin.

8. *Endocrine effects*. Trifloxystrobin does not belong to a class of chemicals known for having adverse effects on the endocrine system. Developmental toxicity studies in rats and rabbits and reproduction study in rats gave no indication that trifloxystrobin might have any effects on endocrine function related to development and reprodufftion. The subchronic and chronic studies also showed no evidence of a long-term effect related to the endocrine system.

9. *Endocrine disruption*. CGA–279202 does not belong to a class of chemicals known for having adverse effects on the endocrine system. Developmental toxicity studies in rats and rabbits and reproduction study in rats gave no indication that CGA–279202 might have any effects on endocrine function related to development and reproduction. The subchronic and chronic studies also showed no evidence of a long-term effect related to the endocrine system.

C. Aggregate Exposure

1. *Dietary Exposure*— i. *Food*. Dietary exposure was calculated using field trial residues generated at the maximum label rate and minimum preharvest interval. Chronic exposure was calculated by taking the mean value of the field trial values, and acute exposure was calculated by using the entire residue distribution in a Monte Carlo analysis. The resulting acute and chronic exposure estimates demonstrated negligible exposure. Using the chronic toxicological endpoint (rat feeding study), the sub-population with the highest predicted exposure was non-nursing infants (< 1 year old) with 1.3% of the reference dose. Acute exposure for the most exposed sub-population, non-nursing infants (< 1 year old), was 2.1% of the acute reference dose at the 99.9th pecentile. These results demonstrate a very large margin of safety for the use of trifloxystrobin on crops.

ii. *Drinking water exposure*— a. *estimated surface drinking water concentration*. The generic expected environmental concentration (GENEEC) estimated surface water concentrations for the proposed Flint and Compass uses contributed little to the overall exposure. These estimated concentrations were not adjusted for the estimated market share or percentage of use area. The two highest day–56 estimated environmetal concentration (EEC) values were 0.06 parts per billion (ppb) and 0.05 ppb provided by the Compass turf and ornamental uses, respectively. According to the EPA ''OPP's Interim Approach for Addressing Drinking Water Exposure,'' the average day–56 value is divided by three when correcting for overestimation of the GENEEC model. This was applied to the ornamental use and the resulting potential exposure via surface water was 0.05 ppb / 3 = 0.017 ppb. The EPA has accepted that the average day–56 EEC value is divided by six in the case when the product is applied to turf and accounts for the

effects of grass/turf in decreasing runoff (EPA, 1998, EPA–730–F–97–002, PB97–137806, page 15). This division by six was used to calculate the potential exposure via surface water from the Compass turf application, 0.06 ppb / 6 = 0.010 ppb. Therefore, the highest potential exposure to trifloxystrobin from surface water is from the Compass ornamental use, 0.017 ppb.

b. *Estimated ground water concentrations.* The screening concentration in ground water (SCI-GROW) estimated ground water concentrations for the proposed Flint and Compass uses also contributed little to the overall exposure. The estimated concentrations were not adjusted for the estimated market share or percentage of use area. In each use scenario, the concentration of trifloxystrobin in ground water was predicted to be below 1 part per trillion. The highest estimated concentration of trifloxystrobin in the ground water was 0.000587 ppb provided by the Compass turf use.

c. *Drinking water levels of concern—acute exposure.* The estimated maximum concentrations of trifloxystrobin in surface water at Peak Day–0 was 2.48 ppb (GENEEC) and 0.000587 ppb in ground water (SCI-GROW). The acute drinking water level of concentration (DWLOC) values were calculated and compared to these estimated water concentrations. Per EPA preference, the 10–day multiple dosing rat teratology study defined the acute NOAEL at 10 mg/kg/day.

From the acute dietary exposure analysis, the lowest Margin of Exposure (MOE) from the use of trifloxystrobin was 1,960 at the 99.9th percentile for the U.S. population and all population subgroups. This indicates a food exposure of less than 0.0051 mg/kg/day for all populations. Based on the EPA's ''Interim Guidance for Conducting Drinking Water Exposure and Risk Assessments'' document (draft 12/2/97), acute drinking water levels of concern ($DWLOC_{acute}$) were calculated for trifloxystrobin. The lowest acceptable Margin of Exposure (MOE) for any pesticide is 100. This value was used in the DWLOC calculations as a conservative approach. Based on this analysis, trifloxystrobin estimated surface water (2.48 ppb) and ground water concentrations (0.000587 ppb) do not exceed the calculated acute DWLOC values (3,497, 3,496, 2,997, 997). Therefore, trifloxystrobin exposures would not exceed the exposure allowable by the risk cup.

d. *Chronic exposure.* The estimated maximum concentrations of trifloxystrobin in surface water at Day–56/3 was 0.017 ppb (GENEEC) and 0.000587 ppb in ground water (SCI-GROW). The chronic DWLOC values were calculated and compared to these estimated water concentrations. The chronic reference dose for trifloxystrobin is 0.025 mg/kg body wt/day, based upon the findings in the rat chronic toxicity study. From the chronic dietary exposure analysis, an exposure estimate of 0.000140 mg/kg body wt/day was determined for the U.S. population and > 0.00032 for all subgroups. Using this information, chronic drinking water levels of concern ($DWLOC_{chronic}$) were calculated for trifloxystrobin. The trifloxystrobin estimated ground water (0.000587 ppb) and surface water (0.017 ppb) concentrations do not exceed the calculated chronic DWLOC values (872, 870, 746, 247). Therefore, trifloxystrobin exposures would not exceed the exposure allowable by the risk cup.

2. *Non-dietary exposure.* Non-dietary exposure to trifloxystrobin is considered negligible as the chemical is intended primarily for commercial and agricultural use. Post-application re-entry exposure to homeowners from professional use on residential ornamentals is considered negligible. For workers handling this chemical, acceptable margins of exposure (in the range of thousands) have been obtained for both acute and chronic scenarios.

D. Cumulative Risk

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 trifloxystrobin would be cumulative with those of any other types of chemicals. Furthermore, the oximinoacetate is a new type of fungicide and no compound in this general chemical class currently has a significant market share. Consequently, Novartis is considering only the potential exposure to trifloxystrobin in its aggregate risk assessment.

E. Safety Determination

1. *U.S. population.* Using the conservative exposure assumptions described above and based on the completeness and reliability of the toxicity data base for trifloxystrobin, Novartis has calculated aggregate exposure levels for this chemical. The calculation shows that only 0.5% of the RfD will be utilized for the U.S. population based on chronic toxicity endpoints. EPA generally has no concern for exposures below 100 percent 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. Novartis concludes that there is a reasonable certainty that no harm will result from aggregate exposure to trifloxystrobin residue.

2. *Infants and children.* Developmental toxicity, manifested as reduced weaning pup weight, enlarged thymus, or fused sternabrae, was observed in the teratology study and 2–generation rat reproduction studies at maternally toxic doses. All of these findings are judged to be non-specific, secondary effects of maternal toxicity. The lowest NOAEL for developmental toxicity was established in the rat reproduction study at 5 mg/kg, a level that is likely to be an overly low estimate (as a result of dose gap) but is still higher than the chronic NOAEL of 2.5 mg/kg on which the RfD is based.

Using the same conservative exposure assumptions as employed for the determination in the general population, Novartis has calculated that the percent of the RfD that will be utilized by aggregate exposure to residues of trifloxystrobin is only 2.1% for non-nursing infants (> l year old) (the most impacted sub-population). Therefore, based on the completeness and reliability of the toxicity data base and the conservative exposure assessment, Novartis concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to trifloxystrobin residues.

F. International Tolerances

No Codex MRL's have been established for residues of trifloxystrobin. Flint has been registered on pome fruit in Switzerland, and Stratego (trifloxystrobin + propiconazole) has been registered on cereals in Switzerland.

[FR Doc. 00–1214 Filed 1–18–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6526–1]

Proposed Prospective Purchaser Agreement Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA), as Amended by the Superfund Amendments and Reauthorization Act, Oronogo-Duenweg Mining Belt Superfund Site, Jasper County, Missouri

AGENCY: Environmental Protection Agency.

ACTION: Notice; request for public comment.