including wheelchair access to the conference room, should contact Mr. Flaak at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: July 6, 2000.

A. Robert Flaak,

Acting Staff Director, Science Advisory Board.

[FR Doc. 00–17617 Filed 7–11–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[PF–949; FRL–6591–8]

Notice of Filing a Pesticide Petition To Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket control number PF–949, must be received on or before August 11, 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–949 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Dani Daniel, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5409; e-mail address: dani.daniel@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.
	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–949. 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, 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?

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 PF–949 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, 1200 Pennsylvania Ave., NW., 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, Crystal Mall #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–949. 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. 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 a 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 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 support 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 requiremements.

Dated: June 29, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary 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 petitioner. 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.

Aventis CropScience

0F6119

EPA has received a pesticide petition 0F6119 from Aventis CropScience, 2 T.W. Alexander Drive, Research Triangle Park, Raleigh, NC, proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of clofentezine in or on the raw agricultural commodity grapes at 0.35 parts per million (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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

APOLLO(r) SC Ovicide/Miticide (active ingredient clofentezine) is registered for use on apples, pears, almonds, walnuts, apricots, cherries, nectarines, and peaches to control European red mites and several spider mite species. It is an environmentally-friendly, IPM-compatible product used at low dose rates, and only once per season. Clofentezine has been shown to be relatively non-toxic in studies conducted on mammals, fish, birds, aquatic invertebrates, predacious and other beneficial mites, bees, algae, and plants by establishing a tolerance for residues of clofentezine in or on the raw agricultural commodity grapes at 0.026 ppm to 0.33 ppm.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of clofentezine has been studied in three crops representative of the use pattern for APOLLO SC: apples (pome fruit), peaches (stone fruit), and grapes (vines/small fruit). In each case, unchanged clofentezine was the major extractable residue present. Non-extractable residues (fiber-bound) were negligible. Minor amounts of 2-chlorobenzonitrile, the major photo-degradation product, were detected, predominantly on the fruit surface. Dissipation of this component may be a significant route in the degradation of clofentezine on the surface of these crops. The nature of the residue in grapes, and in all the other registered crops, is therefore adequately understood. The residue of concern is the parent, clofentezine.

2. *Analytical method.* EPA recently approved an analytical method for clofentezine on apples at a limit of quantitation (LOQ) of 0.01 ppm. In support of that effort, Aventis submitted an independent laboratory validation of the method which involves organic extraction and then cleanup, followed by high-pressure liquid chromatography. This method is suitable for enforcement for the registration of APOLLO SC ovicide/miticide on apples.

For the requested use on grapes, an analytical method similar to the above was previously submitted to the Agency. This method was deemed suitable for enforcement of the tolerances proposed in a previous tolerance petition. Similar analytical methods for enforcement purposes are available for all the other registered crops and relevant animal tissues/milk/fat.

3. *Magnitude of residues.* Extensive field residue trials have been conducted with APOLLO SC on grapes throughout the major growing regions of the United States. Application at 21 days pre-harvest interval (PHI) at the maximum use rate resulted in residues of clofentezine on fresh grapes of 0.026 ppm to 0.33 ppm. In processing studies on grapes which had been treated with APOLLO SC, residues in the processed commodity grape juice were lower than those in the raw agricultural commodity grapes; and residues in raisins were shown to also be lower than those in the raw agricultural commodity.

Residue trials were conducted for APOLLO SC on apples, pears, apricots, cherries, nectarines, peaches, almonds, and walnuts at the maximum use rates and minimum (PHIs) throughout the

major growing regions of the United States. Residues in apples ranged from <0.01 ppm to 0.44 ppm. Residues in pears ranged from <0.01 ppm to 0.2 ppm. Residues in stone fruit ranged from <0.01 ppm to 0.66 ppm. Residues on almond hulls ranged from 0.93 ppm to 2.4 ppm, on almond nut meats from <0.05 ppm to 0.3 ppm, and on walnuts <0.02 ppm. Tolerances were therefore established on apples (0.5 ppm); pears (0.5 ppm); apricots, cherries, nectarines, and peaches (1.0 ppm); almond nutmeats (0.5 ppm); almond hulls (5.0 ppm); and walnuts (0.02 ppm).

Ruminant feeding studies were conducted to determine the magnitude of the clofentezine-derived residues in the tissues and milk of cows. Four groups of three dairy cattle were fed technical clofentezine in the diet at dose levels of 0, 10, 30, and 100 ppm over a period of 28 days. Daily milk samples were taken and at the termination of the study the following organs were analyzed: liver, kidney, heart, muscle, peritoneal fat, and subcutaneous fat. At the feeding level of 10 ppm, residues were 0.3 ppm in liver and <0.05 ppm in kidney, milk, and other tissues. EPA established tolerances for cattle, goats, hogs, horses, and sheep as follows: 0.05 ppm in meat, fat, and meat by-products except liver; 0.4 ppm in liver; and 0.01 ppm in milk.

B. Toxicological Profile

The toxicology of clofentezine has been thoroughly evaluated by EPA as part of previous regulatory actions. The studies are considered to be valid, reliable and adequate for the purposes of evaluating potential health risks and for establishing tolerances. The primary studies submitted in support of the registration of clofentezine are summarized below.

1. *Acute toxicity.* A relatively low degree of acute toxicity and irritation potential. It is classified as toxicity category III for oral, dermal and inhalation toxicity, and toxicity category IV for eye and skin irritation. The acute oral LD_{50} of clofentezine was determined to be >5,2000 milligrams/kilograms (mg/kg) in rats and mice, >3,200 mg/kg in hamsters, and >2,000 mg/kg in beagle dogs. The acute rate dermal LD_{50} was >2,100 mg/kg. Clofentezine is considered to be practically non-irritating to eyes and skin but is considered to be a week skin sensitizer in the guinea pig maximization assay.

APOLLO SC is classified as toxicity category IV for oral toxicity and skin irritation, and as toxicity category III for dermal toxicity and eye irritation. The acute oral LD_{50} of APOLLO SC was determined to be >5,000 mg/kg in rats; the acute dermal LD_{50} in rats was >2,400 mg/kg. APOLLO SC is considered slightly irritating to eyes and skin.

2. *Genotoxicty.* No evidence of genotoxicity was noted in a battery of in vitro and in vivo studies. Studies submitted included Ames Salmonella and mouse lymphoma gene mutation assay, a mouse micronucleus assay, a rat dominant lethal assay, and a gene conversion and mitotic recombination assay in yeast.

3. *Reproductive and developmental toxicity.* A multigeneration rate reproduction study was conducted a dietary concentrations of 0, 4, 40, and 400 ppm. The parental no observed adverse effect level (NOAEL) was 40 ppm based on slightly reduced body weights (bwt), increased liver weights and hepatocellular hypertrophy at 400 ppm. No treatment-related reproductive effects were noted at any dose level.

In a rate developmental toxicity study, clofentezine was administered by gavage at dose levels of 0, 320, 1, 280 and 3,2000 mg/kg/day during gestation days 6 to 20. Evidence of maternal toxicity was noted at 3,200 mg/kg/day and consisted of decreased weight gain, increased liver weights and centrilobular hepatocellular enlargement. No developmental effects were observed at any dose level.

In a rabbit developmental toxicity study, clofentezine was administered by gavage at dose levels of 0, 250, 1,000 and 3,000 mg/kg/day during gestation days 7 to 28. Slight maternal toxicity (decreased maternal food consumption and weight gain) and a slight decrease in fetal weight were noted at 3,000 mg/kg/day. Thus, the NOAEL was considered to be 1,000 mg/kg/day for both maternal and developmental effects.

4. *Subchronic toxicity.* In a preliminary 90-day feeding study designed to select a suitable high dose level for a subsequent chronic rate study, clofentezine was administered to rats at dietary concentrations of 0, 3,000, 9,000 and 27,000 ppm. A significant reduction in weight gain was noted at 9,000 and 27,000 ppm. In addition, a marked, dose-related hepatomegaly and centrilobular hepatocyte enlargement was noted in all treatment groups. In a subsequent 90-day feeding study, clofentezine was administered to rats at dietary concentrations of 0, 40, 400, and 4,000 ppm. Slightly reduced weight gain, alterations in serveral clinical pathology parameters, increased liver, kidney and spleen weights, and centrilobular hepatocyte enlargement were noted at 400 and/or 4,000 ppm. Thus, 40 ppm (~ 2.8 mg/kg/day) was considered to be the NOAEL for this study.

Clofentezine was administered to beagle dogs for 90 days at dietary concentrations of 0, 3,200, 8,000 and 20,000 ppm. Increased liver weights were noted at all dose levels but no histopathological changes nor any other treatment-related effects were observed.

5. *Chronic toxicity.* In a 12-month feeding study, clofentezine was administered to beagle dogs at dietary concetrations of 0, 50, 1,000, and 20,000 ppm. An increase in adrenal and thyroid weights, as well as moderate hepatotoxicity consisting of minimal periportal hepatocyte enlargement with cytoplasmic eosinophilia, hepatomegaly and increased plasma cholesterol, triglycerides and alkaline phosphatase levels, were noted at 20,000 ppm. Evidence of slight hepatotoxicity was also noted at 1,000 ppm. Thus, the NOAEL for this study was considered to be 50 ppm (~1.25 mg/kg/day).

In a 27-month feeding study, clofentezine was administered to rats at dietary concentrations of 0, 10, 40, and 400 ppm. Effects noted at 400 ppm were limited to the liver and thyroid, primarily of males, and consisted of increased liver weights, a variety of microscopic liver lesions (centrilobular hepatocyte hypertrophy and vacuolation, focal cystic hepatocellular degeneration and diffuse distribution of fat deposits), increased serum thyroxine levels, and a slight but statistically significant increase in the incidence of thyroid follicular cell tumors. The NOAEL was considered to be 40 ppm (~2 mg/kg/day).

Clofentezine was not oncogenic to mice when administered for 2 years at dietary concentrations of 0, 50, 500, and 5,000 ppm. Decreased weight gain, increased liver weights, and increased mortality were noted at 5,000 ppm. An increased incidence of eosinophilic or basophilic hepatocytes was noted at 5,000 ppm, and possibly 500 ppm.

Numerous studies were conducted to investigate the mechanism for the increased incidence of male thyroid follicular tumors that was observed in the chronic rat study. These studies suggest that the tumors may have been caused by increased thyroid stimulating hormone (TSH) levels, which, in turn, resulted from clofentezine's liver toxicity.

6. *Animal metabolism.* The metabolism, tissue distribution and excretion of clofentezine have been evaluated in a number of species. In all species, almost all of the administered dose was recovered within 24 to 48 hours after treatment, primarily via the feces. The major route of metabolism

was found to be ring hydroxylation, sometimes preceded by the replacement of a chlorine atom with a methyl-thio group. Blood and tissue levels in the fetuses of pregnant rats that had been treated with clofentezine were much lower than the levels found in the mother, indicating that clofentezine does not readily pass across the placenta. In addition, less than 1% of the administered dose was absorbed through the skin of rats following a 10-hour exposure to a 50 SC (50% suspension concentrate) formulation of clofentezine.

Following oral dosing of a cow and three goats with 14C-labeled clofentezine, the residue in milk was identified as a single metabolite, 4-hydroxyclofentezine. Similarly, 4-hydroxyclofentezine has been shown to be the only metabolite present in fat, liver, and kidney. No unchanged clofentezine or other metabolites were found. Therefore, the nature of the residue in animals is adequately understood. The residues of concern are the combined residues of the parent, clofentezine, and the 4-hydroxyclofentezine metabolite.

7. *Endocrine disruption.* Except for the thyroid mechanistic studies mentioned above, no special studies have been conducted to investigate the potential of clofentezine to induce estogenic or other endocrine effects. However, the standard battery of required toxicity 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. However, with the exception of a slightly increased incidence of thyroid tumors in male rats, no such effects were noted in any of the studies with clofentezine. The male rat is known to be much more susceptible than humans to the carcinogenic effects resulting from thyroid hormone imbalance and/or increased levels of TSH. Therefore, the alterations in thyroid hormone and subsequent thyroid pathological changes, which have been noted following administration of high doses of clofentezine, are considered to be of minimal relevance to human risk assessment, particularly considering the low levels of clofentezine to which humans are likely to be exposed.

C. Aggregate Exposure

1. *Dietary exposure.* Clofentezine is a miticide used on apples, pears, almonds, walnuts, apricots, cherries, peaches, and nectarines. Clofentezine has also been registered recently for use on ornamental plants, however, the product (OVATION (miticide/insecticide) is not being marketed at this time. There are no other non-crop uses. Thus, potential sources of non-occupational exposure to clofentezine would consist only of any potential residues in food and drinking water. There are no acute toxicity concerns with clofentezine. Therefore, only chronic exposures are addressed here.

i. *Food.* A worst case dietary exposure assessment was performed for clofentezine using the dietary exposure evaluation model (DEEM) software (Novigen Sciences, Inc.) and 1994–1996 United States Department of Agriculture (USDA) consumption data. This assessment assumed that 100% of all grapes, apples, pears, almonds, walnuts, apricots, cherries, nectarines, peaches, milk, and the fat, meat, and meat by-products of cattle, goats, horses, sheep, and hogs contained residues at the established and proposed tolerance levels. A more realistic assessment was also conducted using estimates of market share.

ii. *Drinking water.* All EPA environmental fate data requirements have been satisfied. The potential for clofentezine to leach into ground water was assessed in terrestrial field dissipation studies conducted in several locations and in varying soil types. Half-lives ranged from 32.4 to 83 days. No evidence of leaching of parent or degradation products was observed. Based upon these and other studies, EPA concluded that ''clofentezine is a relatively short-lived, non-mobile compound which does not pose a risk to ground water, and will not be expected to accumulate in rotational crops.'' Thus, the potential for finding significant clofentezine residues in drinking water is minimal and the contribution of any such residues to the total dietary intake of clofentezine will be negligible. No maximum contaminant level for clofentezine has been established.

Sufficient ground or surface water monitoring data are not available to perform a quantitative risk assessment for clofentezine at this time. However, EPA previously determined estimated drinking water environmental concentrations (DWECs) in ground and surface water using available environmental fate data and the screening model for ground water (SCI–GROW) and the generic expected environmental concentration (GENEEC) model for surface water. The DWEC of clofentezine in ground water was estimated to be 0.04 parts per billion (ppb) using SCI–GROW, and the DWECs for surface water were estimated to be 6.5 ppb (acute DWEC) and 0.3 ppb (chronic DWEC) using GENEEC. EPA policy allows the 90/56-day GENECC value to be divided by 3 to obtain a value for chronic risk assessment calculations. Therefore, a surface water estimate of 0.1 ppb was used in the chronic risk assessment.

iii. *Chronic exposure.* EPA uses the drinking water level of comparison (DWLOC) as a theoretical upper limit on a pesticide's concentration in drinking water when considering total aggregate exposure to a pesticide in food, drinking water, and through residential uses. DWLOCs are not regulatory standards for drinking water; however, EPA uses DWLOCs in the risk assessment process as a surrogate measure of potential exposure from drinking water. In the absence of monitoring data for pesticides, it is used as a point of comparison against conservative model estimates of a pesticide's concentration in water. Calculated DWLOCs for chronic risks are listed in the following Table 1.

TABLE 1.—SUMMARY OF DWLOC CALCULATIONS-CHRONIC (NON-CANCER SCENARIO)

Population subgroup [1]	Chronic (non-cancer) scenario					
	RfD mg/kg/day	Food exposure mg/kg/day	Maximum water exposure mg/kg/day [2]	SCI–GROW (ppb) [3]	GENEEC (ppb)	DWLOC (ppb)
U.S. population [1]	0.013	0.000346	0.01265	0.04	0.1	442
Northeast region [1]	0.013	0.000380	0.01262	0.04	0.1	441
Non-hispanic other than black or white [1]	0.013	0.000386	0.01261	0.04	0.1	441
Non-nursing infants [2]	0.013	0.001295	0.01171	0.04	0.1	117

TABLE 1.—SUMMARY OF DWLOC CALCULATIONS-CHRONIC (NON-CANCER SCENARIO)—Continued

Population subgroup [1]	Chronic (non-cancer) scenario					
	RfD mg/kg/day	Food exposure mg/kg/day	Maximum water exposure mg/kg/day [2]	SCI–GROW (ppb) [3]	GENEEC (ppb)	DWLOC (ppb)
Children (1–6 yrs) [3]	0.013	0.001333	0.01167	0.04	0.1	233
All infants (<1 yr) [2]	0.013	0.001114	0.01189	0.04	0.1	117

[1] Assume 70 kg bodyweight.
[2] Assume 10 kg bodyweight.
[3] Assume 20 kg bodyweight.

To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DEEM) was subtracted from the RfD to obtain the acceptable chronic (non-cancer) exposure to clofentezine in drinking water. DWLOCs were then calculated using default body weights and drinking water consumption figures.

The estimated average concentration of clofentezine in surface water is 0.1 ppb. This value is less than EPA's DWLOCs for clofentezine as a contribution to chronic aggregate exposures (454 ppb). Therefore, taking into account the present uses and the proposed new use, residues of clofentezine in drinking water (when considered along with other sources of exposure for which reliable data are available) will not result in unacceptable levels of aggregate human health risk.

D. Cumulative Effects

The primary effects observed in the toxicity studies conducted with clofentezine appear to be a result of its potency as an enzyme inducer. Although many other chemicals are also known to induce microsomal enzymes, insufficient information is available at this time to determine whether or not the potential toxic effects from these chemicals are cumulative. Furthermore, realistic estimates of potential non-occupational exposure to clofentezine indicate that such exposures are minimal and far below the levels that might be expected to produce any effects. Thus, any contribution of clofentezine to cumulative risk will not be significant. Therefore, only exposure from clofentezine is being addressed at this time.

E. Safety Determination

1. *U.S. population.* The toxicity and residue data bases for clofentezine are considered to be valid, reliable, and essentially complete. Although clofentezine has been classified by EPA as category C for oncogenicity, quantitative oncogenic risk assessment was considered inappropriate for the following reasons:

a. Evidence of tumors was limited to a single site in one sex of one species and occurred only at the high-dose level.

b. The increased incidence of thyroid follicular tumors was only marginally increased above both concurrent and historical control levels.

c. No evidence of genotoxicity has been observed.

d. Mechanistic data indicate that the thyroid tumors were likely a secondary, threshold-medicated effect associated with clofentezine's liver toxicity. Furthermore, humans are believed to be much less susceptible to this effect than rats. Therefore, no effect on the thyroid pituitary axis or oncogeni response would be expected at exposure levels which did not affect the liver.

e. Clofentexine was recommended as a category D by EPA's scientific advisory panel (SAP) in 1988. Thus, a standard margin of safety approach is considered appropriate to assess the potential for clofentezine to produce both oncogenic and non-oncogenic effects. Based on the previously described data, EPA has adopted an RfD value for clofentezine of 0.0125 mg/kg/day, which was calculate using the NOAEL of 1.25 mg/kg/day from the 1-year dog feeding study and a 100-fold safety factor.

Using the worst-case assumptions of 100% of crop treated and that all crops and animal commodities contain residues of clofentezine at the current tolerance levels, the aggregate exposure of the general population to clofentezine from the established and proposed tolerances utilizes about 9% of the RfD. Using more realistic estimates of percent crop treated, this decreases to less than 3% of the RfD. There is generally no concern for exposures which utilize less than 100% of the RfD because the RfD represents the level at or below which daily aggregate exposure over a lifetime would not pose significant risks to human health. Therefore, there is a reasonable certainty that no harm will result to the general population from aggregate exposure to clofentezine residues.

2. *Infants and children.* Data from rat and rabbit developmental toxicity studies and rat multigeneration reproduction studies are generally used to assess the potential for increased sensitivity of infants and children. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to reproductive and other effects on adults and offspring from prenatal and postnatal exposure to the pesticide.

No indication of increased sensitivity to infants and children was noted in any of the studies with clofentezine. No developmental effects were noted in rats, even at a dose level (3,200 mg/kg/day) that exceeded the 1,000 mg/kg/day limit dose and produced maternal toxicity. In addition, no evidence of reproductive toxicity was noted in the rat multigeneration reproduction study. Slight developmental toxicity (decreased fetal weights) was noted in rabbits, but only at a dose level (3,000 mg/kg/day) that exceeded the EPA limit dose and also produced maternal toxicity.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children to account for prenatal and postnatal toxicity and the completeness of the data base. The toxicology data base for clofentezine regarding potential prenatal and postnatal effects in children is complete according to existing Agency data requirements and does not indicate any developmental or reproductive concerns. Furthermore, the existing RfD is based on a NOAEL of 1.25 mg/kg/day (from the 1-year dog study) which is already more than 800-fold lower than the NOAEL in the rabbit developmental toxicity study. Thus, the existing RfD of 0.0125 mg/kg/day is considered to be appropriate for assessing potential risks

to infants and children and an additional uncertainty factor is not warranted.

Using the conservative exposure assumptions described above (proposed and current tolerances, 100% crop treated, and no adjustments for percent contribution from livestock diet), aggregate exposure to residues of clofentezine are expected to utilize about 48% of the RfD in non-nursing infants, 20% of the RfD in nursing infants, and 36% of the RfD in children aged 1 to 6 years old. Using more realistic estimates of percent crop treated, the percent of RfD utilized is less than or equal to 10% for these population subgroups. These numbers would be lowered further if anticipated residues and/or an adjustment for percent contribution from livestock diet were utilized rather than tolerance values. Therefore, there is a reasonable certainty that no harm will result to infants or children from aggregate exposure to clofentezine residues.

F. International Tolerances

Codex tolerances have been established for clofentezine on a wide variety of crops, including apples. The following maximum residue levels (MRLs) were adopted by the Codex Committee on Pesticide Residues (CCPR) in April 1988, except as noted in parentheses:

Commodity	MRL (mg/kg)
Cattle meat	0.05
Cattle, edible offal	0.1
Cattle, milk	0.01
Citrus fruits	0.5 (1995)
Cucumber	1.0 (1991)
Currants	0.01 (1993)
Eggs (poultry)	0.05
Grapes	1.0 (1995)
Pome fruits	0.5
Poultry, edible offal	0.05
Poutry meat	0.05
Stone fruits	0.2
Strawberry	2.0

This value, 1.25 mg/kg/day, was calculated by EPA using their standard conversion factor for food consumption. The NOAEL based upon actual food consumption in the study is 1.7 mg/kg/day.

[FR Doc. 00–17356 Filed 7–11–00; 8:45 am]

BILLING CODE 6560–50–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6734–2]

Notice of Availability for Draft Guidance on the Use of Emissions Reductions From Motor Vehicles Operated on Low-Sulfur Gasoline as New Source Review (NSR) Offsets for Tier 2/Gasoline Sulfur Refinery Projects in Nonattainment Areas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: The EPA is making available for public review and comment a preliminary draft of its pending guidance on the use of emissions reductions resulting from motor vehicles operated on low sulfur gasoline as NSR offsets for Tier 2/Gasoline Sulfur Refinery Projects in nonattainment areas.

On February 10, 2000, EPA issued new emissions standards (''Tier 2 standards'') for all passenger vehicles, including sport utility vehicles, minivans, vans and pick-up trucks. To ensure the effectiveness of low emissions control technologies in these vehicles, this rule also sets new standards to significantly reduce the sulfur content in gasoline. In order to meet these sulfur-in-gasoline requirements, many refiners will have to make modifications to their existing facilities, which could be subject to the major permitting requirements under parts C and D of the Clean Air Act. For a refinery located in an area designated nonattainment, the acquisition of emissions offsets is one of the prerequisites for receiving the construction permit authorizing the major modification. To provide greater certainty and to expedite the NSR permitting process for refinery projects undertaken in nonattainment areas to comply with the new gasoline sulfur requirements, EPA intends to provide guidance to explain how States can use some of the motor vehicle emissions reductions resulting from use of low sulfur gasoline as NSR offsets.

A draft of EPA's guidance is available for public review and comment. The EPA does not intend to respond to individual comments, but rather to consider the comments from the public in the preparation of the final guidance.

DATES: The comment period on the draft guidance will close on August 11, 2000.

ADDRESSES: Written comments should be sent to Pamela J. Smith, Information Transfer and Program Integration Division (MD–12), Office of Air Quality Planning and Standards, U.S. EPA, Research Triangle Park, North Carolina 27711, telephone 919–541–0641, telefax 919–541–5509 or E-mail *smith.pam@epa.gov.*

FOR FURTHER INFORMATION CONTACT: Dan deRoeck, Information Transfer and Program Integration Division (MD–12), Office of Air Quality Planning and Standards, U.S. EPA, Research Triangle Park, North Carolina 27711, telephone 919–541–5593, telefax 919–541–5509 or E-mail *deroeck.dan@epa.gov.*

SUPPLEMENTARY INFORMATION: A copy of the draft guidance document may be obtained by calling or E-mailing Pamela J. Smith. The draft guidance may also be downloaded from the NSR Web Site *http://www.epa.gov/ttn/nsr* under the topic ''What's New on NSR.''

Dated: July 5, 2000.

John S. Seitz,

Director, Office of Air Quality Planning and Standards.

[FR Doc. 00–17615 Filed 7–11–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–00576A; FRL–6589–6]

Pesticides; Policy Issues Related to the Food Quality Protection Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: EPA is announcing the availability of the revised version of the pesticide science policy document entitled ''Available EPA Information on Assessing Exposure to Pesticides in Food—A User's Guide.'' This notice is the nineteenth in a series concerning science policy documents related to the Food Quality Protection Act of 1996 and developed through the Tolerance Reassessment Advisory Committee.

FOR FURTHER INFORMATION CONTACT: Kathleen Martin, Environmental Protection Agency (7509C), 1200 Pennsylvania, Ave., NW., Washington, DC 20460; telephone number: (703) 308–2857; fax number: (703) 305–5147; e-mail address: martin.kathleen@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be potentially affected by this action if you manufacture or formulate pesticides. Potentially affected categories and entities may include, but are not limited to: