

There are no reports of ecological or human health hazards caused by *Muscodor albus* strain QST 20799. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. The limited survival of *Muscodor albus* QST 20799, the rapid dissipation of the volatile compounds produced, and lack of acute toxicity indicate that both the potential hazard and the dietary exposure to human adults, infants and children associated with the use of *Muscodor albus* strain QST 20799 are low.

2. *Non-dietary exposure.* The potential for non-dietary inhalation and dermal exposure to the general population, including infants and children, is unlikely as the pesticide is proposed for agricultural or postharvest use sites. The major intended use of *Muscodor albus* strain QST 20799 is to fumigate soil and harvested crops for the purposes of disease control.

*Muscodor albus* strain QST 20799 has limited survivability once its carrier nutrient source is exhausted. Volatile compounds produced by *Muscodor albus* strain QST 20799 are not of toxicological concern and dissipate rapidly in the environment. Personal protective equipment (PPE) mitigates the potential for exposure to applicators and handlers of the proposed products, when used in agricultural settings.

The results of toxicity testing indicate there is no risk to human health or the environment from *Muscodor albus* strain QST 20799. There are no reports of ecological or human health hazards caused by *Muscodor albus* strain QST 20799. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. The limited survival of *Muscodor albus* strain QST 20799, the rapid dissipation of the volatile compounds produced, and lack of acute toxicity indicate that both the hazard and the exposure associated with the use of *Muscodor albus* strain QST 20799 are low. Non-dietary exposures would not be expected to pose any quantifiable risk because there are no detectable residues of toxicological concern.

#### E. Cumulative Exposure

It is expected that, when used as proposed, *Muscodor albus* strain QST 20799 would not result in residues that are of toxicological concern. The major

intended use of *Muscodor albus* strain QST 20799 is to fumigate soil and harvested crops for the purposes of disease control. *Muscodor albus* strain QST 20799 has limited survivability once its carrier nutrient source is exhausted. Volatile compounds produced by *Muscodor albus* strain QST 20799 are not of toxicological concern and dissipate rapidly in the environment. The results of toxicity testing indicates there is no risk to human health or the environment from *Muscodor albus* strain QST 20799.

There are no reports of ecological or human health hazards caused by *Muscodor albus* strain QST 20799. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. The limited survival of *Muscodor albus* strain QST 20799, the rapid dissipation of the volatile compounds produced, and lack of acute toxicity indicate that both the hazard and the exposure associated with the use of *Muscodor albus* Strain QST 20799 are low.

#### F. Safety Determination

1. *U.S. population.* Acute toxicity studies have shown that *Muscodor albus* strain QST 20799 is not toxic, pathogenic, infective or irritating to mammals. The major intended use of *Muscodor albus* strain QST 20799 is to fumigate soil and harvested crops for the purposes of disease control. *Muscodor albus* strain QST 20799 has limited survivability once its carrier nutrient source is exhausted. Volatile compounds produced by *Muscodor albus* strain QST 20799 are not of toxicological concern and dissipate rapidly in the environment. The results of toxicity testing indicates there is no risk to human health or the environment from *Muscodor albus* strain QST 20799. There are no reports of ecological or human health hazards caused by *Muscodor albus* strain QST 20799. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. The limited survival of *Muscodor albus* strain QST 20799, the rapid dissipation of the volatile compounds produced, and lack of acute toxicity indicate that both the hazard and the exposure associated with the use of *Muscodor albus* strain QST 20799 are low. There is a reasonable certainty of no harm to the general U.S.

population from exposure to this active ingredient.

2. *Infants and children.* As mentioned above, it is expected that, when used as proposed, *Muscodor albus* strain QST 20799 would not result in residues that are of toxicological concern. There is a reasonable certainty of no harm for infants and children from exposure to *Muscodor albus* strain QST 20799 from the proposed uses.

#### G. Effects on the Immune and Endocrine Systems

To date there is no evidence to suggest that *Muscodor albus* strain QST 20799 functions in a manner similar to any known hormone, or that it acts as an endocrine disrupter.

#### H. Existing Tolerances

There is no EPA tolerance for *Muscodor albus* strain QST 20799.

#### I. International Tolerances

There is no Codex alimentarius commission maximum residue level (MRL) for *Muscodor albus* strain QST 20799.

[FR Doc. 04-7476 Filed 4-6-04; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0073; FRL-7349-9]

### Forchlorfenuron; Notice of Filing a Pesticide Petition to Establish an Extension of a Time-Limited 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 ID number OPP-2004-0073, must be received on or before May 7, 2004.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone

number: (703) 305-7740; e-mail address: [giles-parker.cynthia@epa.gov](mailto:giles-parker.cynthia@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 28522)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any 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 Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP-2004-0073. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the **"Federal Register"** listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA

Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or on paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical

objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

###### C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also, include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2004-0073. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID number OPP-2004-0073. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID number OPP-2004-0073.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP-2004-0073. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

#### *D. How Should I Submit CBI to the Agency?*

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does

not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed 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 ID 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 Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA 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 requirements.

Dated: March 22, 2004.

**Betty Shackelford,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

#### **Summary of Petition**

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the KIM-C1, LLC, c/o Siemer & Associates, Inc., 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.

**KIM-C1, LLC, c/o Siemer & Associates, Inc.,**

*PP 7G4906*

EPA has received a pesticide petition (PP 7G4906) from KIM-C1, LLC, c/o Siemer & Associates, Inc., 4672 W. Jennifer, Street, Suite 103, Fresno, CA 93722, proposing, pursuant to section 408(d) the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing an extension of a time-limited tolerance for forchlorfenuron (CPPU) in or on the raw agricultural commodities almonds, apples, blueberries, figs, grapes, kiwi fruit, pears, and plums at 0.01 parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) or 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.

#### *A. Residue Chemistry*

1. *Plant metabolism.* <sup>14</sup>C radiolabel studies were conducted on apples, grapes, and kiwi fruit. Results of these three studies showed that the metabolism of CPPU in apples, grapes, and kiwi fruit is similar, if not identical. Metabolism of CPPU in these crops involved hydroxylation of the phenyl-ring to form 3-hydroxy-CPPU or 4-hydroxy-CPPU followed by conjugation with glucose to form B-glycosides. These studies were conducted using CPPU at 15 parts per million (ppm) and 75 ppm. Most of the residue remained on the treated surface and was primarily associated with the pulp tissue. Very little radioactivity was found in the juice.

2. *Analytical method.* Two analytical methods both based on high performance liquid chromatography (HPLC) procedures have been developed. The first used a visible ultraviolet (UV) detector while the second used a mass spec detector. Since the mass spec detector is capable of both qualitative as well as quantitative measurement it is the preferred method. The level of quantification (LOQ) in whole grape fruit was 0.01 ppm; the level of detection (LOD) was 0.003 ppm. In grape juice, the LOQ was 0.002 ppm and the LOD 0.0007 ppm (0.7 parts per billion (ppb)). In raisins the LOQ was 0.01 ppm and the LOD was 0.003 ppm.

3. *Magnitude of residues.* The magnitude of the residues in the crops are anticipated to be below the level of quantification which, based on whole fruit, will be 0.01 ppm.

#### B. Toxicological Profile

A full battery of toxicology testing including studies of acute, subchronic, chronic, oncogenicity, developmental, reproductive and genotoxicity effects is available for CPPU. The acute toxicity of CPPU is low by all routes. The lowest subchronic study no observable adverse effect level (NOAEL) value is 16.8 milligrams/kilogram/day (mg/kg/day) obtained from the dog 90-day toxicity study. Chronic studies indicate that CPPU is not carcinogenic. The lowest chronic dietary NOAEL is 7 mg/kg/day from male rats fed CPPU for 104 weeks. CPPU showed no evidence of developmental toxicity in rats and rabbits. In a rat reproduction study, reproductive effects were only observed at maternally toxic doses. Finally, genetic toxicity studies indicate that CPPU is not genotoxic. For the purpose of dietary risk analysis, 0.07 mg/kg/day is proposed for the chronic population adjusted dose (cPAD). The cPAD is based on a chronic endpoint of 7 mg/kg/day which is the NOAEL for males from the rat chronic/oncogenicity feeding study and an uncertainty factor of 100. No acute toxicity endpoint could be identified and, therefore, an acute dietary risk assessment is considered unnecessary.

1. *Acute toxicity.* The acute toxicity of CPPU is low by all routes. The battery of acute toxicity studies place CPPU into Toxicity Category III. CPPU has low acute toxicity when administered orally, dermally or via inhalation to rats. It is not a skin irritant and is only a mild eye irritant. CPPU is not a skin sensitizer.

2. *Genotoxicity.* The genotoxic potential of CPPU was studied *in vitro* in bacteria and mammalian cells and *in vivo* in the unscheduled DNA synthesis test. The test systems assayed did not

show any evidence of genotoxicity except in the bacterial mutagenicity assay, strain TA1535, without metabolic activation. The weight of the evidence indicates that CPPU does not possess significant genotoxicity concerns.

3. *Reproductive and developmental toxicity.* Developmental effects of CPPU were studied in rats and rabbits and multigenerational effects on reproduction were studied in rats.

i. *Rat developmental.* In the developmental toxicity study conducted with rats, CPPU was administered by gavage at levels of 0, 100, 200, and 400 mg/kg/day. The maternal and developmental NOAELs are 200 mg/kg/day based on reduced body weights, body weight gain and food consumption and an increased incidence of alopecia in dams. There were no developmental effects.

ii. *Rabbit developmental.* In the rabbit developmental toxicity study, gavage doses of 0, 25, 50, 100 mg/kg/day were administered. Maternal toxicity (decreased body weight and body weight gains) was observed at 50 mg/kg/day and above. The maternal NOAEL is 25 mg/kg/day and the developmental NOAEL is 100 mg/kg/day. There were no developmental effects.

iii. *Reproduction.* In the rat reproduction study, CPPU was administered in the diet at levels of 0, 150, 2,000 and 7,500 ppm for two generations. There were no adverse effects of CPPU on reproductive success. Parental toxicity consisted of clinical signs, inhibition of body weight gain, reduced food consumption, and macroscopic and microscopic effects in the kidney. Reproductive toxicity in the highest dose consisted of slightly reduced live litter sizes in the F<sub>2</sub> litters. In the pups, body weights and survival (late lactation period) were reduced and at the high dose, pup mortality and emaciation were increased. The parental, pup and reproductive NOAELs are 150 ppm, 150 ppm and 2,000 ppm, respectively.

4. *Subchronic toxicity.* Subchronic studies have been conducted with CPPU in the rat, mouse and dog.

i. *Rats:* CPPU technical was tested in rats in a 3-month study at dietary levels of 0, 200, 1,000 and 5,000 ppm. Observations were decreased body weight, body weight gain and food efficiency. The NOAEL males is 5,000 ppm (400 mg/kg/day) and in females is 1,000 ppm (84 mg/kg/day).

ii. *Mice.* A 13-week feeding study in mice was conducted at dose levels of 0, 900, 1,800, 3,500 and 7,000 ppm. Effects included decreased body weight and food consumption, increased relative liver weight and lymphocytic cell

infiltration in the kidneys. The NOAEL is 3,500 ppm (609 mg/kg/day in males and 788 mg/kg/day in females).

iii. *Dogs:* A 13-week dietary toxicity study was conducted in beagle dogs at dose levels of 0, 50, 500, and 5,000 ppm. Effects included decreased body weight gain, food consumption and food efficiency. The NOAEL for both sexes was 500 ppm (16.8 mg/kg/day in males and 19.1 mg/kg/day in females).

5. *Chronic toxicity.* CPPU has been tested in chronic studies with dogs, rats, and mice.

i. *Rats.* In a 104-week combined chronic/oncogenicity study in rats, CPPU was administered at dose levels of 0, 150, 2,000, and 7,500 ppm in the diet. Findings were decreased body weight, body histopathological effects in the kidney. No oncogenicity was found. The NOAEL for this study is 150 ppm (7 mg/kg/day in males and 9 mg/kg/day in females).

ii. *Mice.* CPPU was administered in the diet to mice for 78-weeks at dose levels of 0, 10, and 1,000 mg/kg/day. Observations were decreased body weight and body weight gain, food consumption, increased kidney weights and incidence of chronic kidney histopathological lesions. The NOAEL for both sexes is 10 mg/kg/day.

iii. *Dogs.* In a 12-month study, CPPU was administered in the diet to dogs at dose levels of 0, 150, 3,000 and 7,500 ppm. Observations included reduced body weight, body weight gain and food consumption and various hematology changes. The NOAEL for both sexes was 3,000 ppm (87 mg/kg/day in males and 91 mg/kg/day in females).

iv. *Carcinogenicity.* CPPU did not produce carcinogenicity in chronic studies with rats or mice. The oncogenicity classification of CPPU will be "E" (no evidence of carcinogenicity for humans).

6. *Animal metabolism.* A rat metabolism study indicates that CPPU is almost completely absorbed and most of the <sup>14</sup>C-CPPU-derived radioactivity is rapidly eliminated primarily via the urine. The majority of the metabolism of CPPU was via hydroxylation of the phenyl ring. The sulfate conjugate of hydroxyl CPPU was the major metabolite excreted in the urine, accounting for as much as approximately 96% of the urinary radioactivity. Tissue residues accounted for less than 1% of the administered dose at 168 hours post-dosing.

7. *Metabolite toxicology.* Metabolites occur at levels below 0.1 ppm and, therefore, are below levels required to be assayed in animal testing.

8. *Endocrine disruption.* Potential endocrine effects. No special studies to

investigate the potential for endocrine effects of CPPU have been performed. However, as summarized above, a large and detailed toxicology data base exists for the compound including studies in all required categories. These studies include acute, sub-chronic, chronic, developmental, and reproductive toxicology studies including detailed histology and histopathology of numerous tissues, including endocrine organs, following repeated or long-term exposures. These studies are considered capable of revealing endocrine effects. The results of all of these studies show

no evidence of any endocrine-mediated effects and no pathology of the endocrine organs. Consequently, it is concluded that CPPU does not possess estrogenic or endocrine disrupting properties.

#### C. Aggregate Exposure

1. *Dietary exposure.* The dietary exposure assessment was conducted by Environs for foods containing forchlorfenuron: CAS Number: 68157–60–8 (CPPU).

i. *Food.* A reference dose (RfD) was calculated using the most sensitive

species data available from the toxicological testing. This RfD 0.08 mg/kg/day/based on a temporary tolerance of 0.01 ppm, was used to calculate the impact of the estimated residue levels with results from treatment of the indicated crops. The table below shows the theoretical maximum residue concentrations (TMRC) of CPPU on or in the listed crops requested in the EUP request.

Theoretical maximum residue concentrations for CPPU for the crops listed in the EUP request

	All - Apples	All + Apples	Total Exposure	
			Mg/kg bwt/day	Percent of RfD
General U.S. populations (all seasons)	.000005	.000011	.000016	.02
Non-nursing infants	.000029	.000064	.000093	.12
Children (1 to 6 years of age)	.000010	.000048	.000058	.07
Children (7 to 12 years of age)	.000005	.000017	.000022	.03

The anticipated use rate of 17 grams of CPPU per acre applied once per year yielding residue levels in the very low ppb range indicates that less than 1% of the RfD would be consumed in aggregate with all of these crops. The crop contributing greatest to the percent of the RfD related to the most sensitive of the population, i.e., all nursing

infants (less than 1-year old) would represent 1/10<sup>th</sup> of 1% of the RfD. Making the same risk exposure calculations, it is shown that there is no significant impact on reducing the RfD by using almonds, apples, blueberries, figs, grapes, kiwi fruit, pears, and plums in aggregate. Combining the RfD consumption from the large group of

crops with that of apples would exceed 1% of the reference dose only slightly if the total acreage of all these crops were treated. The intention of this experimental use permit is not to treat all of the various crops listed; the following table shows the requested acreage of each crop.

Crop	Acreage Requested	% Total Acreage
Grape	3,500	0.53
Kiwi fruit	250	0.05
Almond	50	0.01
Apple	50	0.14
Blueberries	50	--
Figs	50	0.40
Plums	50	0.03
Pears	20	0.15

This program would permit development of requisite data to assure safe and efficacious use and, yet, not subject any segment of the public to a health risk.

Acute (1-day) exposure would not represent any hazard since no acute exposure was identified in this risk assessment.

ii. *Drinking water.* The very low use rate of CPPU, i.e., 17 grams active ingredient (a.i.) or less per acre if used constantly for 20 years would apply less

than a pound of CPPU per acre during that 20 year period. Computer modeling, using the conservative pesticide root zone model (PRZM) means of analysis has shown that no CPPU would reach ground water, even in sandy loam soils. The results of this risk analysis supported an unambiguous conclusion of "essentially zero risk to ground water" even under reasonable worst-case assumptions. Concentrations are not predicted to exceed 15 to 20 ppb of CPPU in the soil in the upper soil

horizons, even following yearly applications for as long as 30 years. No secondary exposure is anticipated as a result of contamination of drinking water.

2. *Non-dietary exposure.* No non-dietary exposure is expected since CPPU is not anticipated to be found in the drinking water. This material does not translocate in plants and thus secondary exposure through plants growing in soil receiving CPPU is not anticipated. The extremely low

application rates will not result in significant buildup in the environment. Data indicate that any parent material of CPPU left in the soil will be strongly bound to soil particles and will not move.

#### *D. Cumulative Effects*

There are no cumulative effects expected since CPPU is not taken up by plants from the soil. It slowly degrades to mineral end points. Its low use rates and infrequent applications are not conducive to buildup in the environment.

#### *E. Safety Determination*

1. *U.S. population.* As pointed out above in dietary exposure-food, the percentage of the RfD consumed by treating the subject crops represents only slightly more than 1% of the estimated safe level for the most sensitive segment of the population, non-nursing infants.

2. *Infants and children.* No developmental, reproductive or fetotoxic effects have been associated with CPPU. The calculation of safety margins with respect to these segments of the population were taken into consideration in the TMRC estimates with respect to the risk associated with the percentage of the reference dose being consumed.

#### *F. International Tolerances*

There is no Codex maximum residue level established for CPPU. However, CPPU is registered for use on grapes and other crops in Japan, Chile, Mexico, and South Africa.

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## ENVIRONMENTAL PROTECTION AGENCY

[FRL-7644-5]

### Interpretation of Regulations Related to Payments to Consultants Under Grants

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice.

**SUMMARY:** EPA's Appropriation Act limits the Agency's participation in the amounts recipients pay to consultants to the maximum daily rate of pay for Level IV of the Executive Schedule. Recently, questions have been posed regarding how to interpret both the statutory consultant fee limitation and the EPA regulation. The purpose of the attached document is to provide EPA grant specialists and project officers guidance

regarding the Agency's interpretation of the appropriation act language as well as the regulatory provisions. This notice explains for EPA applicants and recipients how EPA applies the payment limit.

**DATES:** The attached document becomes effective on April 7, 2004.

#### **FOR FURTHER INFORMATION CONTACT:**

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**SUPPLEMENTARY INFORMATION:** EPA's appropriation act limits the Agency's participation in the amounts recipients pay consultants to the maximum daily rate of pay for Level IV of the Executive Schedule. This limit was first established in EPA's Fiscal Year 1978 appropriation act and Congress clarified the scope of the limit in EPA's Fiscal Year 1979 appropriation act. The Agency applies the limit to EPA assistance agreements through EPA's Uniform Administrative Requirements and Agreements with Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations (40 CFR 30.27(b)) and Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments (40 CFR 31.36(j)). In addition, EPA's regulations provide that contracts with firms for services which are awarded using the prescribed procurement requirements are not subject to the consultant fee limitations (40 CFR 30.27(b) and 31.36 (j)).

Recently, there have been some questions raised regarding EPA's application of the limit. The purpose of the attached document is to provide EPA grant specialists and project officers guidance regarding the Agency's interpretation of the appropriation act language as well as the regulatory provisions. This notice provides information to EPA applicants and recipients to make them aware of how EPA applies the payment limit. This guidance clarifies existing EPA policy and applies to all EPA assistance agreements, regardless of award dates.

This document reiterates the limits under EPA's appropriation act and makes clear that:

- If a recipient, or its contractor, chooses to pay more than the consultant fee cap (\$524.72 per day in 2004), the recipient must use its own funds to pay the difference. Also, if the assistance agreement includes a recipient indirect cost rate, the recipient can apply it only to allowable costs, not to amounts in excess of the consultant fee cap. Finally, recipients cannot use the amount in excess of the consultant fee cap for cost

sharing purposes. (The consultant fee cap does not apply to reasonable consultant overhead or travel direct costs. Recipients may reimburse these direct costs in accordance with their normal practices.)

- If a consultant is paid on an hourly basis, EPA will not participate in more than the hourly equivalent of the rate (\$65.59 per hour for 2004), nor will EPA participate in more than the maximum daily rate if a consultant paid on an hourly basis works more than 8 hours in a day. Further, if a consultant works less than 8 hours in a day, EPA will not participate in more than the hourly equivalent rate for each hour worked even if the consultant is paid on a daily basis. There may be cases where recipients believed that EPA would participate in the maximum daily rate, even if the consultant worked less than 8 hours in a day. In such cases, recipients and EPA Grants Management Offices should document the situation and may request the Director, Grants Administration Division, to waive the hourly limit under section 9 of the EPA Order.

- The consultant fee cap does not apply to contracts with firms or individuals that are awarded pursuant to the procurement procedures under 40 CFR Parts 30 and 31 (40 CFR 30.27(b) and 40 CFR 31.36(j)(2)) so long as the terms of the contract do not provide the recipient with responsibility for the selection, direction, and control of the individual(s) who will be providing services under the contract. Conversely, the consultant fee cap does apply to contracts with firms or individuals that are awarded under the procurement procedures of 40 CFR Parts 30 and 31 if the terms of the contract provide the recipient with responsibility for the selection, direction, and control of the individuals who will be providing services under the contract at an hourly or daily rate of compensation. The cap does not apply to fixed priced or lump sum contracts for specified products such as reports or delivery of a training course. Applicants or recipients who have questions concerning whether an individual is a consultant subject to the fee cap should contact the appropriate EPA project officer or grants specialist.

- The consultant fee cap does not apply to contracts for technical advisory services awarded competitively under EPA's Superfund Technical Assistance Grant (TAG) program regulations at 40 CFR 35.4205 provided that the terms of the contract indicate that the technical advisor has the discretion of an independent contractor and do not vest the TAG recipient with responsibility