Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and record keeping requirements.

Dated: March 28, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.472 is amended by revising ''corn, field, fodder,'' ''corn, field, forage,'' and ''corn, field, grain'' and alphabetically adding the remaining commodities to the table in paragraph (a) to read as follows:

§ 180.472 Imidacloprid; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration/Revocation Date
* * * * * * *		
Beans, edible, podded	1.0	None
Beans, succulent, shelled	1.0	None
* * * * * * *		
Cilantro	3.5	None
Citrus, dried pulp	5.0	None
Citrus, fruits, group	0.7	None
Corn, field, fodder	0.20	None
Corn, field, forage	0.10	None
Corn, field, grain	0.05	None
Corn, sweet, forage	0.10	None
Corn, sweet, (K+CWHR)	0.05	None
Corn, sweet, stover	0.20	None
* * * * * * *		
Greens, turnip	3.5	None
* * * * * * *		
Vegetable, leaf petiole, subgroup	6.0	None
* * * * * * *		

* * * * *

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BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301109; FRL–6773–2]

RIN 2070–AB78

Fenpyroximate; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for the combined residues of fenpyroximate benzoic acid, 4-[[[(*E*)-(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl) methylene]amino] oxy]methyl]-, 1,1-dimethylethyl ester] and its z-isomer benzoic acid, 4-[[[[(*Z*)-(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl) methylene]aminio]oxy]methyl]-,1,1-dimethylethyl ester)] in or on wine grapes and hops. Nihon Nohyaku requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act (FQPA) of 1996. The tolerance will expire April 12, 2004.

DATES: This regulation is effective April 10, 2001. Objections and requests for hearings, identified by docket control number OPP–301109, must be received by EPA on or before June 11, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301109 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Melody Banks, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5413; and e-mail address: banks.melody@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 codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing 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'', ''Regulations and Proposed Rules,'' 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/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301109. The official record consists of the documents specifically referenced in this action, 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 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.

II. Background and Statutory Findings

In the **Federal Register** of February 18, 1999 (64 FR 8090) (FRL–6059–9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP) for tolerance by Nihon Nohyaku, Nihon Noyaku Co., 2-5 Nihonsbashi 1-Chome, Chuoku, Tokyo 103, Japan. This notice included a summary of the petition prepared by Nihon Nohyaku, the registrant.

The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the insecticide, fenpyroximate and its z-isomer, in or on wine grapes at 1.0 parts per million (ppm) and hops at 10 ppm. The tolerance will expire April 12, 2004.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of fenpyroximate and its z-isomer on wine grapes at 1 ppm and hops at 10 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by fenpyroximate are discussed below following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

Fenpyroximate is toxicity category II for oral toxicity (the only acute study conducted). Acute studies are not required for import tolerances.

Subchronic and chronic studies in the rat resulted in decreased body weight and weight gain (also observed in the mouse carcinogenicity study). There were hematological effects and decreased plasma butyryl cholinesterase and plasma acetylcholinesterase at higher doses. In the subchronic and chronic dog studies there was a bradycardia which did not appear to increase in severity with time. Also at this dose diarrhea, decreased body weight, body weight gains and food consumption were reported. At higher doses, there was also emesis. The high dose in the subchronic study resulted in first and second degree heart block, increased urea concentration, decreased glucose, and altered plasma electrolyte levels among other signs of toxicity.

Male and female rats were given dietary levels of compound in feed for a period of either 13 weeks or 104 weeks. Thirteen week doses ranged from 20 ppm to 500 ppm (1.47 mg/kg/day to 36.91 mg/kg/day), while 104 week doses ranged from 10 ppm to 150 ppm (0.4 mg/kg/day to 7.57 mg/kg/day). In the subchronic study, both sexes in the 100 and 500 ppm groups had impaired growth performance, reduced food intake, and decreased body weights and body weight gains. Body weight gains for the 100 ppm groups were 85% of the control weight gains, and for the 500 ppm groups were 33-37% of the control gains. At 500 ppm in both sexes, hematocrit, hemoglobin, and red blood cell counts were higher, and white blood cell counts were lower than the control values. Total plasma proteins were also lower. The 500 ppm females had alkaline phosphatase activities that were 123% higher and plasma butyryl cholinesterase and plasma acetylcholinesterase activities that were 72-73% lower compared to the controls. Treatment-related effects noted in the gross pathology of the 500 ppm groups were facial staining in both sexes; encrustations of the muzzle and persistent hyaloid arteries in males; and dorsal/ventral hair loss, skin encrustations, skin masses, perineal staining, and skin exfoliation in females. The LOAEL was 6.57 mg/kg/day (100 ppm) for rats, based on decreased body weight gains in both sexes. The NOAEL

was 1.3 mg/kg/day (20 ppm). In the chronic study, similar toxicity was observed in males and females in the 75 or 150 ppm groups. Toxicity included depressed growth rates that were 86% and 78% of controls in males and females, respectively, at 150 ppm in the carcinogenicity phase after 104 weeks. Low growth rates were accompanied by less than a 10% decrease in mean food consumption and a 12-14% reduction in food efficiency at the 150 ppm level when compared with controls. The LOAEL for systemic toxicity was 75 ppm (3.08 and 3.79 mg/kg/day in males and females, respectively), and the NOAEL was 25 ppm (0.97 mg/kg/day for males and 1.16 mg/kg/day for females) based on decreased body weight gain. Under the conditions of this study, there was no evidence of carcinogenic potential. Dosing was considered adequate based on dose-related decreases in body weight gain and feed consumption in both sexes relative to the controls.

In the mouse carcinogenicity study, doses ranged from 25 to 800 ppm (approximately 2.4 - 73.0 mg/kg/day) for up to 18 months. Toxicity was similar to that observed in the rat studies and included dose-related decreases at 100 ppm and above in mean body weight, weight gain (9, 37, and 52% (male); 18, 44, and 60% (female) for increasing doses) and in mean feed consumption. Based on decreased body weights and food consumption observed at 100 ppm and higher dose levels, the chronic LOAEL was established at 100 ppm (9.5 mg/kg/day for male mice and 10 mg/kg/day for females). The NOAEL was 25 ppm (2.4 mg/kg/day for male mice and 2.5 mg/kg/day for females). Under the conditions of this study, there was no evidence of carcinogenic potential. Dosing was considered adequate based on dose-related decreases in body weight gain and feed consumption in both sexes relative to the controls.

Dogs were given fenpyroximate in capsules for either 13 weeks with doses ranging from 2 to 50 mg/kg/day or for 52 weeks with doses ranging from 0.5 to 15 mg/kg/day. In the subchronic study, two high dose females were sacrificed *in extremis* during weeks 4 or 5 after a period of treatment-related inappetence and body weight loss. Both sexes at all treatment levels exhibited slight bradycardia (slow heart rate) and a dose-related increase in diarrhea. Emaciation and torpor were observed in the 2 mg/kg/day females and in both sexes from the 50 mg/kg/day groups. Emesis was observed in both sexes at 10 mg/kg/day and above. The 50 mg/kg/day male and in all treated female groups had reduced body weights and body weight gains (7% (male); 6, 14 and 24% (female)). Food consumption was also decreased in all female groups. In males, glucose levels and total white blood cell counts were lower at 10 mg/kg/day and above. Prothombin time values were prolonged and urea concentrations were higher in the 50 mg/kg/day females. Absolute and relative adrenal gland weights and relative liver weights were increased in the 50 mg/kg/day males and females. In the 50 mg/kg/day females, there was depleted hepatocytic glycogen and fine vacuolation of the cell cytoplasm in the renal medullary rays. One or both of the 50 mg/kg/day females sacrificed *in extremis* exhibited first and second degree heart block, increased urea concentration, low glucose concentration, disturbances in plasma electrolyte levels, depleted hepatocytic glycogen, and fine vacuolation of the cell cytoplasm in the renal medullary rays. The LOAEL was 2 mg/kg/day based on slight bradycardia and an increased incidence of diarrhea in both sexes. In females only, there were reduced food consumption, body weight, body weight gain, emaciation, and torpor. No NOAEL was established.

In the chronic dog study, similar signs of toxicity were observed. Male beagles in the 5.0 or 15.0 mg/kg/day treatment groups had diarrhea more frequently (especially during the first 3-4 months of the study). Males in the 15.0 mg/kg/day treatment group were an average 12% lighter, consumed 10% less food than the controls, and had heartbeat rates 30% slower ≤24 hours after dosing compared to the controls at study termination. Female beagles in the 5.0 or 15.0 mg/kg/day treatment groups had diarrhea more frequently than control animals. The LOAEL was 15.0 mg/kg/day for both male and female beagles, based on diarrhea, bradycardia, decreased cholesterol, body weight gain and food consumption in males and vomiting, diarrhea, excessive salivation and decreased cholesterol in females. The NOAEL was 5.0 mg/kg/day.

In a 2-generation reproduction study, fenpyroximate was administered continuously in the diet at approximate doses ranging from 0.83 to 8.60 mg/kg/day for females and from 0.67 to 9.92 mg/kg/day for males (with some variation depending on generation) (dietary concentrations ranging 10 to 100 ppm) for 2 successive generations (1-litter/generation). No treatment-related effects were observed in the 10 or 30 ppm treatment groups. The systemic NOAEL was 1.99 and 2.44 mg/kg/day (30 ppm) for males and females, respectively. The systemic LOAEL was 6.59 and 8.60 mg/kg/day (100 ppm) for males and females, respectively, based on decreased body weights of both sexes during the premating period. The mean premating body weights were slightly depressed at 30 ppm, in the P_1 males and females (5-6%) and significantly depressed in F_1 males (14% compared to controls; $p < 0.01$); body weight gains for the F_1 males were also significantly lower ($p < 0.01$). Food consumption at 30 ppm for P_1 and F_1 males was also slightly depressed. The mean weights of the 100 ppm P_1 females were significantly reduced during gestation, and weight gain was 12% lower than in controls at gestation day 20 ($p < 0.05$); by the end of lactation the weights were similar to control. The mean body weights of the F_1 females were also lower than controls during gestation (6-9%), but recovered to control levels by the end of lactation. For reproductive effects, the NOAEL was 2.44 mg/kg/day (30 ppm). The reproductive LOAEL was 8.60 mg/kg/day (100 ppm) based on decreased lactational weight gain in both generations of pups. Mean pup weights were similar in all groups at day 0 of lactation, but the weight gains in both generations were decreased at 100 ppm; mean weights at day 25 were 24% and 15% lower than control ($p < 0.01$) in F_1 and F_2 pups, respectively.

In a developmental toxicity study, rats were dosed by gavage at dose levels of 0, 1.0, 5.0, or 25 mg/kg/day from days 6 through 15 of gestation. The maternal NOAEL was 5 mg/kg/day and the LOAEL was 25 mg/kg/day based on marginal maternal toxicity (decreased body weight gain and decreased food consumption). This included a marginal depression in maternal body weight and food at 25 mg/kg/day. It is apparent that animals could have tolerated higher dose levels of the test material. However, since developmental toxicity was observed as noted below, the lack of overt maternal toxicity does not affect acceptability of the study. The high dose as a LOAEL was also supported by the range-finding study. The developmental NOAEL was 5.0 mg/kg/day. The developmental LOAEL was 25 mg/kg/day based on increase in the fetal incidence of additional thoracic ribs. Additional historical control data (and an additional evaluation of the study data on this effect - combined bilateral and unilateral incidence by fetus/litter) is requested for increased number of thoracic ribs in order to determine whether this is in fact a treatment-related effect.

In a developmental toxicity study, rabbits were dosed by gavage at dose levels of 0, 1.0, 2.5, or 5.0 mg/kg/day from days 6 through 19 of gestation. Both the maternal LOAEL and the NOAEL were greater than 5.0 mg/kg/

day, the highest dose level tested. The developmental LOAEL and the NOAEL were also greater than 5.0 mg/kg/day. The Hazard Identification Assessment Review Committee (HIARC) considered the occurrence of folded retina in the high dose fetuses to be questionable. There was, however, a borderline maternal body weight effect at the 5.0 mg/kg/day dose in the range-finding study.

Fenpyroximate is not considered to be a mutagen with the currently available data base. The overall quality of the toxicology data base is good with the exception of the two developmental toxicity studies. EPA is requiring that the developmental toxicity studies in rats and rabbits with fenpyroximate be repeated at doses which are adequate to characterize developmental susceptibility. Confidence in the hazard and dose response is also good with the exception noted above. Although there are no data gaps, the two developmental toxicity studies must be repeated, and the additional historical control data must be submitted as requested for the existing rat developmental study.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10x to account for interspecies differences and 10x for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10x to account for interspecies differences and 10x for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC, as shown in the following Table 1:

TABLE 1.— SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FENPYROXIMATE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study
Acute dietary females - 13 to 50	NOAEL = 5 UF = 100 FQPA SF = 10	LOAEL = 25 mg/kg/day is based on increase in the fetal incidence of additional thoracic ribs. Acute RfD = 0.05 mg/kg/day Acute PAD = 0.005 mg/kg/day	Developmental rat
Chronic (non-cancer) dietary	NOAEL= 0.97 mg/kg/day UF = 100 FQPA SF = 1	LOAEL = 75 ppm (3.08 and 3.79 mg/kg/day in males and females), based on decreased body weights, accompanied by reduced food efficiency and a slight decrease in mean food consumption. Chronic RfD = 0.01 mg/kg/day Chronic PAD = 0.01 mg/kg/day	Two year rat feeding study
Chronic (cancer) Dietary	''Not likely'' to be carcinogenic to humans via relevant routes of exposure		
Short-, Intermediate, and Long-Term (Dermal)	NOAEL = NA	NA	NA
Short-, intermediate, and long-term (Inhalation)	NOAEL = NA	NA	NA

NA = Not applicable. This request is for an import tolerance; therefore, applicator exposure risk assessments are not required.

EPA has conducted a risk assessment for the acaricide fenpyroximate benzoic acid, 4-[[[[(*E*)-(1,3-dimethyl1-5-phenoxy-1*H*-pyrazol-4-yl) methylene]amino]oxy]methyl]-, 1,1-dimethylethylethyl ester] and its z-isomer in support of the establishment of time-limited tolerances on imported wine grapes and hops. EPA has evaluated toxicology and residue data for fenpyroximate submitted by Nihon Nohyaku.

Fenpyroximate is registered for use on grapes in Germany, France, Portugal, and Italy and on hops in Germany. The

maximum application rate for fenpyroximate is 130 grams active ingredient hectare (g/a.i./ha) (0.12 lb. a.i./acre) for grapes and 263 g a.i./ha (0.23 lb. a.i./acre) for hops. The preharvest interval (PHI) is 21 days for hops and 14 days for grapes.

The proposed use is limited to imported wine grapes and hops only. Therefore, no water or occupational or residential exposure assessments are required.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances are being established (40 CFR 180.566) for the residues of fenpyroximate, in or on Wine grapes and hops. Risk assessments were conducted by EPA to assess dietary exposures from fenpyroximate in food as follows.

i. *Dietary exposure and risk analysis*. A dietary exposure analysis using the Dietary Exposure Evaluation Model (DEEM) was completed (Memo, J. Rowell, D271394, January 11, 2001) for acute and chronic (non-cancer). The DEEM analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-91 Continuing Surveys for Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made: tolerance level residues were used and 100% Crop Treated (CT) was assumed for all commodities. Default DEEM concentration factors were used for all processed food forms.

The acute dietary exposure analysis estimates the distribution of single-day exposures for the U.S. population and certain subgroups. Each analysis assumes uniform distribution of fenpyroximate for the commodities on which fenpyroximate is used.

The Tier 1 acute analysis was performed for females 13-50 years old using tolerance levels and assuming 100% CT information for all commodities. EPA retained the 10x safety factor for the females 13-50 years old in acute dietary risk assessments only, therefore the acute RfDs for these subgroups have been adjusted to reflect the aPAD. The aPAD for females 13-50 years old is 0.005 (0.05 mg/kg/day ÷ 10 = 0.005 mg/kg/day). For acute dietary risk, EPA's level of concern is >100% aPAD. Dietary exposures and associated acute risk for females 13-50 are shown in the following Table 2:

TABLE 2.—SUMMARY OF RESULTS OF ACUTE DEEM ANALYSIS FOR FENPYROXIMATE AT THE 95TH PERCENTILE

Subgroups	Exposure (mg/kg/day)	% aPAD
Females (13+ years old/pregnant/not nursing)	0.000000	0
Females (13+ years old/nursing)	0.000098	2
Females (13-19 years old/not pregnant/not nursing)	0.000000	0
Females (20+ years old/not pregnant/not nursing)	0.000208	4
Females (13-50 years old)	0.000160	3

The results of the acute analysis indicate that at the 95th percentile the acute dietary risk associated with the proposed uses of fenpyroximate is below EPA's level of concern.

ii. *Chronic Exposure*. In conducting this chronic dietary risk assessment the DEEM analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1991 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Tolerance level residues were used and 100% CT was assumed for all commodities. Default DEEM concentration factors were used for all processed food forms.

The chronic dietary exposure analysis used mean consumption (3-day average) data. The Tier 1 chronic analysis was performed using tolerance levels and assuming 100% CT information for all commodities. For chronic risk assessments, the 10x safety factor was removed (reduced to 1x), therefore the chronic RfD and cPAD are equivalent. The cPAD for the U.S. population and all subgroups is 0.01. For chronic dietary risk, EPA's level of concern is >100% cPAD. Dietary exposures for the U.S. population and other subgroups are presented in Table 3. The other subgroups included in Table 3 represent the highest dietary exposures for their respective subgroups (i.e., children, infants, and male subgroups).

TABLE 3.—SUMMARY OF RESULTS FROM CHRONIC DEEM ANALYSIS OF FENPYROXIMATE

Subgroups	Exposure (mg/kg/day)	% cPAD
U.S. population (48 states)	0.000099	1
All infants (>1 yr old)	no exposure	–
Children 1-6 yrs. old	0.000002	0
Females 13+ years old (nursing)	0.000166	2
Males 20+ yrs old	0.000138	1

The results of the chronic analysis indicate that the chronic dietary risk associated with the proposed uses of fenpyroximate is below EPA's level of concern for the U.S. population and all subgroups.

iii. *Cancer dietary risk*. Fenpyroximate was classified as ''not likely'' to be carcinogenic to humans via relevant routes of exposure using the proposed new guidelines (RfD document dated February 19, 1997).

Therefore, no cancer dietary exposure analysis was performed.

2. *Dietary exposure from drinking water*. The use on wine grapes and hops is an import use only. At present there is one registered use for fenpyroximate in the U.S. for ornamental greenhouse use. No run-off to surface water or drainage to ground water is expected.

Therefore, a drinking water exposure assessment is not necessary. If domestic uses are added in the future, OPP will reassess the potential impacts of fenpyroximate on drinking water as a part of the aggregate risk assessment process.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Fenpyroximate is not registered for use on any sites that would result in residential exposure.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether fenpyroximate has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, fenpyroximate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fenpyroximate has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Prenatal and postnatal sensitivity*. Although there are no toxicity data gaps according to EPA's Subdivision F Guideline requirements for an import tolerance, EPA is requiring that the developmental toxicity studies in rats and rabbits be repeated at doses which are adequate to characterize developmental susceptibility. EPA is retaining the 10x FQPA safety factor due to uncertainties in evaluating potential susceptablilty following *in utero* exposure as a result of inadequate developmental toxicity studies in both species (rat and rabbit). This should be applied only to females 13 to 50 for the determination of acute dietary risk because the potential effects occur only during *in utero* exposure and are not postnatal effects.

The FQPA safety factor is reduced to 1x for chronic dietary risk assessment because the developmental toxicity studies (for which we have uncertainty) are not relevant to chronic risk assessments (*in utero* exposure is not chronic) for the following reasons: (1) The NOAEL used in deriving the RfD was based on decreased body weight gain in rats in the rat chronic toxicity/carcinogenicity study; (2) the developmental effects on which the FQPA factor is based were seen in pregnant animals; and (3) the developmental effects are considered to be ''acute'' effects. There was no evidence of increased susceptibility in the multigeneration reproduction study, a longer study.

EPA concluded that the doses selected in the developmental toxicity studies with rats and rabbits should have been higher since the highest doses produced only marginal maternal toxicity, or were supported by marginal toxicity in range finding studies. Additionally, there is some question as to the significance (due to maternal toxicity or to direct fetal effects) of fetal variations in both species (rats-increased thoracic ribs, rabbits-questionable increase in retinal folding). Therefore, EPA could not dismiss the possibility of increased susceptibility in both species.

EPA further concluded that the data from the 2-generation reproduction study in rats provided no indication of quantitative or qualitative increased susceptibility since maternal toxicity and reproductive toxicity occurred at the same dose.

A developmental neurotoxicity study was not recommended because neurotoxic compounds of similar structure were not identified and there was no evidence of neurotoxicity in the current toxicity data base.

iii. *Conclusion*. The toxicological data base for fenpyroximate is adequate to support a time-limited import tolerance. Fenpyroximate exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA is retaining the 10x FQPA safety factor due to uncertainties in evaluating potential susceptablilty following *in utero* exposure as a result of inadequate developmental toxicity studies in both species (rat and rabbit). This should be applied only to females 13 to 50 for the determination of acute dietary risk because the potential effects occur only during *in utero* exposure and are not postnatal effects.

2. *Acute risk*. The Aggregate acute risk is the same as the acute risk set forth in Unit III.C.1.i. The other registered use does not contribute to aggregate acute risk.

3. *Chronic risk*. The chronic acute risk is the same as the chronic risk set forth in Unit III.C.1.i. The other registered use does not contribute to chronic acute risk.

4. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to fenpyroximate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (example: gas chromotography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There is neither a Codex proposal, nor Canadian or Mexican limits for residues of fenpyroximate in wine grapes and hops. Therefore, a compatibility issue is not relevant to the proposed tolerances.

C. Conditions

The petitioner is required to perform storage stability studies in grape juice and grapes. As Chile is a major source of wine, additional grape residue data from this country and a translation of the Chilean label are required. Additional information on uses of fenpyroximate in Mexico and a translation of the Mexician label are required. The specificity of Method DFG S 19 should be demonstrated by performing an interference study with all pesticides for which tolerances are established on grapes and hops. Alternatively, a very specific confirmatory method (e.g., uses of MS detection) should be submitted. The two developmental toxicity studies must be repeated and historical control data submitted for the existing rat developmental study.

V. Conclusion

Therefore, a tolerance with an expiration of 3 years after date of publication in the **Federal Register** is established for residues of fenpyroximate, benzoic acid, 4-[[[(*E*)-)1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl) methylene]amino]oxy]methyl-, 1,1-dimethylethyl ester], and its z-isomer in or on wine grapes at 1.0 ppm and hops at 10 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301109 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before June 11, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301109, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any

enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq*., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 27, 2001.

Joseph J. Merenda,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), (346a) and 371.

2. Section 180.566 is added to read as follows:

§ 180.566 Fenpyroximate; tolerances for residues.

(a) *General*. This regulation establishes a time-limited tolerance for the combined residues of fenpyroximate benzoic acid, 4-[[[(*E*)-(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl) methylene] amino] oxy]methyl]-, 1,1-dimethylethyl ester] and its z-isomer benzoic acid, 4-[[[[(*Z*)-(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl) methylene]aminio] oxy]methyl]-, 1,1-dimethylethyl ester)] in or on wine grapes and hops. These tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Hops[1]	10	April 12, 2004.
Wine grapes[1]	1.0	April 12, 2004.

[1]There are no U.S. registrations on Hops and Wine grapes.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 01–8806 Filed 4–9–01; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 3160

[WO–310–1310–01–24 1A–PB]

RIN 1004–AC54

Oil and Gas Leasing: Onshore Oil and Gas Operations

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule; partial further delay of effective date and request for comments.

SUMMARY: In accordance with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled ''Regulatory Review Plan,'' 66 FR 7701 (January 24, 2001), the Bureau of Land Management (BLM) temporarily delayed for 60 days until April 10, 2001, the effective date of the rule entitled ''Oil and Gas Leasing: Onshore Oil and Gas Operations,'' published in the **Federal Register** on January 10, 2001 (66 FR 1883). This action partially delays the April 10, 2001, effective date published in the **Federal Register** on February 8, 2001 (66 FR 9527), by delaying the effective date for 120 days of 43 CFR 3162.2–7 of the final rule. It also delays for 120 days removal of current 43 CFR 3162.2(a). We do so in order to seek further public comments.

DATES: The effective date for removal of 43 CFR 3162.2(a) and the addition of 43 CFR 3162.2–7, originally published in the **Federal Register** on January 10, 2001 (66 FR 1892–1893), delayed until April 10, 2001, in the **Federal Register** on February 8, 2001 (66 FR 9527), is further delayed for 120 days until August 8, 2001, for the purpose of seeking further public comments. You may submit comments on or before June 11, 2001.

ADDRESSES: If you wish to comment, you may submit comments by any one of these methods:

(1) You may mail comments to the Bureau of Land Management, Administrative Record, 1849 ''C'' Street, NW, Room 401LS, Washington, D.C. 20240.

(2) You may deliver comments to Room 401, 1620 L Street, NW, Washington, D.C. 20036.

(3) You may also comment via the Internet to WOComment@blm.gov. Please submit comments as an ASCII file avoiding the use of special characters and any form of encryption. Please also include ''ATTN: AC54'' and your name and return address in your Internet message. If you do not receive a confirmation from the system that we have received your Internet message, contact us directly at (202) 452–5030.

FOR FURTHER INFORMATION CONTACT: Donnie Shaw, Fluid Minerals Group, Bureau of Land Management, Mail Stop 401LS, 1849 ''C'' Street, NW, Washington, D.C. 20240; telephone (202) 452–0382 (Commercial or FTS). Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8330, 24 hours a day, seven days a week, except holidays, for assistance in reaching Mr. Shaw.

SUPPLEMENTARY INFORMATION: To the extent that 5 U.S.C. 553 applies to this action, the action is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, the Department's implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. 553(b)(3)(B) and 553(d)(3), in that seeking public comment is impractical, unnecessary and contrary to the public interest inasmuch as it cannot be accomplished before April 10, 2001. However, the Department is seeking public comment on whether further rulemaking to modify the promulgated rule is needed. The effective date was delayed for 60 days with a new effective date of April 10, 2001, to give Department officials the opportunity for further review and consideration of new regulations, consistent with the Assistant to the President's memorandum of January 20, 2001. The Department is further delaying the effective date of two discrete provisions to permit further review, consideration, and public comments on the addition of § 3162.2–7 published on January 10, 2001. The provisions of § 3162.2–7, concerning the joint and several liability of multiple lessees or operating rights owners for drainage protection, including compensatory royalties, were the subject of intense debate during the notice and comment period on this rule. The BLM is delaying the effectiveness of this provision, and retaining in effect for another 120 days the current provision of § 3162.2(a) concerning the duty of operating rights owners to protect the lessor against drainage, in order to consider further comments on these issues from the regulated industry, Indian mineral owners, State, local and Tribal governments, and members of the general public.

Commenters raised a serious legal issue as to the compatibility of the joint and several provisions of § 3162.2–7 with provisions of the Royalty Simplification and Fairness Act. The Secretary wants to permit the public an opportunity to present more extensive legal argument as to whether it is correct to interpret the Royalty Simplification and Fairness Act to not apply to compensatory royalty payments because they are not royalties or payment obligations, but damages for nonperformance of an obligation to drill a protective well. See the legal analysis at 63 FR 1937 and 66 FR 1886.

We particularly encourage the public to respond to the following questions:

1. Should the obligation to drill a protective well be considered a joint and several liability of the holders of operating rights? If the duty to drill a protective well is not joint and several, what proportion of the interest holders in the lease must be unable or unwilling to contribute to the cost of the well to justify a refusal of the operator or operating rights owner to drill a protective well?

2. If the obligation to drill a protective well is joint and several among operating rights owners, does BLM's acceptance of compensatory royalties in satisfaction of that obligation convert the obligation into a ''payment obligation'' owed pro rata under the Royalty Simplification and Fairness Act? Was the Royalty Simplification and Fairness Act intended to cover compensatory royalty payments?

3. If one or more parties who hold undivided interest in the record title or operating rights for the same lease do not exercise due diligence in fulfilling its share of drainage obligations for that lease, who should be responsible for compensating the Government for those unfulfilled obligations?

4. Does the treatment of the drainage protection obligation as a joint and several obligation affect the willingness of investors to acquire operating rights interests in a lease? Does it affect the willingness of lessees to retain an interest in record title when transferring operating rights to another party?

5. Does the classification of the drainage obligation as joint and several, or proportionate to interest, depend on