regulations is authorized under 33 CFR 117.35.

Dated: November 8, 2000.

Gerald M. Davis,

Captain, U.S. Coast Guard, Acting Commander, First Coast Guard District.

[FR Doc. 00–29804 Filed 11–20–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301075; FRL–6752–4]

RIN 2070–AB78

Fenhexamid; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of fenhexamid in or on pears. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on pears. This regulation establishes a maximum permissible level for residues of fenhexamid in this food commodity. The tolerance will expire and is revoked on December 31, 2002.

DATES: This regulation is effective November 21, 2000. Objections and requests for hearings, identified by docket control number OPP–301075, must be received by EPA on or before January 22, 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 VII. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301075 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6463; and e-mail address: madden.barbara@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 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/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301075. 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, 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

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the fungicide fenhexamid, (*N*-2,3-dichloro-4-hydroxyphenyl)-1-methyl cyclohexanecarboxamide), in or on pears at 15 parts per million (ppm). This tolerance will expire and is revoked on December 31, 2002. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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. . . .''

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Fenhexamid on Pears and FFDCA Tolerances

According to the Applicant, development of thiabenzadole resistance in California Botrytis populations has left packing houses without an effective tool to control the disease. Registered alternatives include thiabenzadole, captan, Bio-Save *Pseudomonas syringae*, Aspire *Candida oleophila*, chlorine and ozone. Testing in the laboratory and in the field suggests that thiabenzadole resistance may be developing above historic levels. Captan is not considered a viable alternative because several countries have banned the import of captan-treated fruit. The Applicant additionally claims that the unpredictable efficacy and results of biological controls have kept the pear industry from adopting this technology, and chlorine and ozone are claimed to burn the fruit. While the Agency does not fully agree with all of the arguments presented by the Applicant, EPA concurs that emergency conditions could exist for some packing houses in this State. On September 21, 2000, the Applicant availed of itself the authority to declare a crisis exemption under section 18 of FIFRA for the postharvest use of fenhexamid on pears to control gray mold.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of fenhexamid in or on pears. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 2002, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on pears after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether fenhexamid meets EPA's registration requirements for use on pears or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of fenhexamid by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than California to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for fenhexamid, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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).

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 fenhexamid and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of fenhexamid in or on pears at 15 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

The dose at which no observed adverse effect level (NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which lowest observed adverse effect level (LOAEL) of concern are identified 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 level of concern (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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are

not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for fenhexamid used for human risk assessment is shown in the following Table 1:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary females 13–50 years of age	None	None	None
Acute Dietary general population including infants and children	None	None	None
Chronic Dietary all populations	NOAEL = 17 mg/kg/day UF = 100 Chronic RfD = 0.17 mg/kg/day	FQPA SF = 3 cPAD = chronic RfD ÷ FQPA SF = 0.057 mg/kg/day	1–Year Feeding Study in Dogs LOAEL = 124/133 mg/kg/day in males/females, based on decreased RBC counts, hemoglobin and hematocrit and increased Heinz bodies in RBC. Also, in females, increased absolute and relative adrenal weights correlated with histopathological observations of increases in incidence and severity of intracytoplasmic vacuoles in the adrenal cortex.
Short-Term Dermal (1 to 7 days) (Residential)	Dermal NOAEL = 1,000 mg/kg/day (limit dose) (dermal absorption rate = 20%)	LOC for MOE = 300 (Residential)	21–Day Dermal Study - Rabbits No rabbits died during this study. No skin irritation was observed in any treated animals. There were no compound related effects on clinical signs, body weight, food consumption, hematology, clinical chemistry, organ weights, or gross and histologic pathology. Dermal administration of fenhexamid was well tolerated by both sexes for 21–days at the limit dose of 1,000 mg/kg/day.
Intermediate-Term Dermal (1 week to several months) (Residential)	Dermal NOAEL = 1,000 mg/kg/day (limit dose) (dermal absorption rate = 20%	LOC for MOE = 300 (Residential)	21–Day Dermal Study - Rabbits No rabbits died during this study. No skin irritation was observed in any treated animals. There were no compound related effects on clinical signs, body weight, food consumption, hematology, clinical chemistry, organ weights, or gross and histologic pathology. Dermal administration of fenhexamid was well tolerated by both sexes for 21–days at the limit dose of 1,000 mg/kg/day.
Long-Term Dermal (several months to lifetime) (Residential)	None	None	None
Short-Term Inhalation (1 to 7 days) (Residential)	None	None	None
Intermediate-Term Inhalation (1 week to several months) (Residential)	None	None	None
Long-Term Inhalation (several months to lifetime) (Residential)	None	None	None
Cancer (oral, dermal, inhalation)	None	None	The Agency has classified Fenhexamid as a ''not likely'' carcinogen. This classification is based on the lack of evidence of carcinogenicity in male and female rats as well as in male and female mice and on the lack of genotoxicity in an acceptable battery of mutagenicity studies.

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.553) for the residues of fenhexamid, in or on a variety of raw agricultural commodities including grapes, raisins and strawberries. Risk assessments were conducted by EPA to assess dietary exposures from fenhexamid in food as follows:

i. *Acute exposure*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. No acute dietary endpoint has been identified. Therefore, no assessment was conducted for acute dietary exposures.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: use of tolerance level residues and 100% of the crop was treated.

iii. *Cancer*. The Agency has classified fenhexamid as a ''not likely'' carcinogen. Therefore, no exposure assessment was conducted to assess cancer concerns.

2. *Dietary exposure from drinking water*. The use pattern associated with the emergency exemption (use of fenhexamid as a postharvest treatment on pears) is not expected to impact water resources. However, the Agency is required to perform an aggregate risk assessment which includes all registered uses of fenhexamid that would lead to exposure to humans through drinking water. Therefore, the Agency estimated environmental concentrates in drinking water from the use of fenhexamid on strawberries to determine the aggregate risk assessment.

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for fenhexamid in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of fenhexamid.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a % RfD or % PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to fenhexamid they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the estimated environmental concentrations (EECs) of fenhexamid for chronic exposures are estimated to be 4.8 parts per billion (ppb) for surface water and 0.0007 ppb for ground water.

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). Fenhexamid 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 fenhexamid 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, fenhexamid 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 fenhexamid 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).

C. 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Developmental toxicity studies*. In a developmental toxicity study in rats, maternal toxicity (marginally decreased body weight gain and decreased food consumption during the treatment period only) was observed at the LOAEL of 1,044 milligrams/kilograms/day (mg/kg/day) (only dose level tested). The NOAEL for maternal toxicity was <1,044 mg/kg/day. At the same dose level of 1,044 mg/kg/day, no treatment-related signs of developmental toxicity were observed in the fetuses. The NOAEL for developmental toxicity was 1,044 mg/

kg/day and the LOAEL was not established (>1,044 mg/kg/day). Although a NOAEL was not determined for maternal toxicity in this study, the study need not be repeated because the effects at the LOAEL were only marginal and of minimal toxicological concern.

In a developmental toxicity study in rabbits, the NOAEL for maternal toxicity was 100 mg/kg/day and the LOAEL was 300 mg/kg/day, based on alterations of excretory products (discolored urine, scant feces, small scybala), decreased body weight gain and decreased food consumption (especially during the first week of dosing) and decreased placental weight. At the next higher dose level of 1,000 mg/kg/day, the maternal effects were increased in severity. A decreased gestation index, based on a slightly increased incidence of abortions and total litter resorptions, was not considered to be treatment-related because the incidences of abortions and resorptions fell within the historical control range submitted with the study. The NOAEL for developmental toxicity was 300 mg/kg/day and the LOAEL was 1,000 mg/kg/day, based on slightly decreased fetal body weights (<5%) in males only and increased delayed ossification in several bones (especially the 5th sternal segments and the 15th caudal vertebrae).

iii. *Reproductive toxicity study*. In a 2–generation (1 litter/generation) reproduction study in rats, there were no treatment-related effects on mortality, clinical signs, behavior or reproductive parameters for adult (parent) animals. The NOAEL for reproductive toxicity was 1,814/2,043 mg/kg/day (M/F) (HDT). The NOAEL for parental toxicity was 38/45 mg/kg/day (M/F) and the LOAEL was 406/477 mg/kg/day (M/F). In males at the LOAEL of 406 mg/kg/day, increased serum creatinine levels and decreased kidney weights indicated mild kidney damage and increased serum alkaline phosphatase levels and decreased liver weights indicated mild liver damage. In females at the LOAEL of 477 mg/kg/day, increased serum alkaline phosphatase levels and very slightly increased serum GGT levels suggested mild liver damage. At the next higher dose level of 1,814/2,043 mg/kg/day (M/F)(HDT), the effects observed at the LOAEL in both males and females were slightly increased in severity. In addition, decreased body weight, increased food consumption, and increased serum GGT levels were observed in males and decreased body weights, increased food consumption, increased serum urea nitrogen levels, increased serum creatinine levels and decreased kidney weights were observed in females. The NOAEL for neonatal toxicity was 38/45 mg/kg/day (M/F) and the LOAEL was 406/477 mg/kg/day (M/F). At the LOAEL of 406/477 mg/kg/day, treatment-related decreased pup body weights were observed in F_1 pups on postnatal days 14 and 21 and in F_2 pups on postnatal days 7, 14 and 21. At the next higher dose level of 1,814/2,043 mg/kg/day (M/F) (HDT), the decreased pup body weights were increased in severity. In addition, an increased mortality was observed among the post weaning F_1 pups selected to be F1 parents (possibly due to the small size of the pups at weaning, which was 30% less than controls).

The results in this reproduction study are equivocal with respect to evaluating the possibility of increased susceptibility of pups, as compared to adults, to fenhexamid. On the basis of NOAELs/LOAELs, no increased susceptibility of pups to fenhexamid was demonstrated in this study. However, the severity of the effects observed in the pups may have been greater than that observed in the adults at the same dose levels. In addition, several other toxicological considerations, including possibly increased intake of test material in pups resulting from intake in both milk and diet during the lactation period and possibly decreased levels of UDP-glucuronyltransferase enzyme in pups (a normally occurring phenomenon in rat pups) resulting in decreased metabolism or ''detoxification'' of test material, contributed to the uncertainty of the determination.

iv. *Prenatal and postnatal sensitivity.* The available Agency Guideline studies indicate no increased susceptibility of rat or rabbit fetuses to *in utero* exposure to fenhexamid. In the prenatal developmental toxicity study in rats, no evidence of developmental toxicity was seen even at the highest dose tested. In the prenatal developmental toxicity study in rabbits, developmental toxicity was seen only in the presence of maternal toxicity.

In the 2–generation reproduction study in rats, quantitatively (i.e., based on NOAELs/LOAELs in parental animals versus offspring), there was no evidence of increased susceptibility of the pups. Qualitatively, however, there was evidence of increased susceptibility based on the comparative severity of effects at the LOAEL (406 mg/kg/day): Parental toxicity was characterized as alterations in clinical chemistry parameters and decreased organ weights without collaborative histopathology; while offspring toxicity was manifested as significantly decreased pup body weights in both generations during the lactation period (on lactation days 7, 14, and 21 in the F_2 generation and lactation days 14 and 21 in the F_1 generation offspring)

v. *Conclusion*. The Agency has determined that a safety factor is required for fenhexamid because qualitatively, there was evidence of increased susceptibility based on the comparative severity of effects in the 2–generation reproduction study in rats. The effects on pups were of concern because:

1. Significant pup body weight decreases were observed in both the F_1 and the F_2 generations.

2. The pup body weight decreases in the F_2 generation were observed during early lactation (lactation day 7 through day 21) when the pups are exposed to the test material primarily through the mother's milk.

3. The pup body weight decreases in the F_1 generation were observed during late lactation (lactation days 14 through 21) when the pups are exposed to the test material through the mother's milk and through the feed.

4. In the metabolism study on fenhexamid, glucuronidation of fenhexamid was clearly demonstrated to be the single major route of metabolism, detoxification and excretion of fenhexamid in adult male and female Wistar rats. The demonstrated poor glucuronidation capacity of rat pups between days 7 and 21 (in a referenced study) indicates a possibly increased sensitivity of pups and serves to support a concern for neonatal toxicity.

However, the Agency has reduced the FQPA safety factor to 3x because:

1. The toxicology data base is complete for the assessment of the effects of fenhexamid following *in utero* and/or postnatal exposure.

2. There is no indication of increased susceptibility of rat or rabbit fetuses to *in utero* exposure in the prenatal developmental toxicity studies with fenhexamid.

3. The increased susceptibility demonstrated in the 2–generation reproduction study was only qualitative (not quantitative) evidence and was observed only in the presence of parental toxicity.

4. The qualitative offspring effect was limited to decreased body weight and no other adverse effects (e.g., decreased pup survival, behavioral alterations, etc) were observed.

5. Adequate data are available or conservative modeling assumptions are used to assess dietary food and drinking water exposure.

6. There are currently no residential uses for fenhexamid.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [(e.g., allowable chronic water exposure (mg/kg/day) = cPAD − (average food + chronic non-dietary, non-occupational exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the U.S. EPA Office of Water are used to calculate DWLOCs: 2 Liter(L)/70 kilogram (kg) (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to fenhexamid in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of fenhexamid on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. No acute dietary endpoint has been identified. Therefore, no risk assessment was conducted for acute dietary exposures.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fenhexamid from food will utilize 7% of the cPAD for the U.S. population, 65% of the cPAD for all infants, less than 1 year old and 16% of the cPAD for children, 1–6 years old, the subpopulation of children at greatest exposure. There are no residential uses for fenhexamid that result in chronic residential exposure to fenhexamid. In addition, despite the potential for chronic dietary exposure to fenhexamid in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of fenhexamid in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2:

TABLE 2. — AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FENHEXAMID

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.057	7	4.8	0.0007	1,900
Children, 1–6 years	0.057	16	4.8	0.0007	480
All infants, < 1 year	0.057	65	4.8	0.0007	190

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fenhexamid is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). Fenhexamid is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which were previously addressed.

5. *Aggregate cancer risk for U.S. population.* The Agency has classified Fenhexamid as a ''not likely'' carcinogen. Therefore, no risk assessment was conducted to assess cancer concerns.

6. *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 fenhexamid residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Bayer AG Method 00362, a high performance liquid chromatography method with electrochemical detection, is the enforcement method for fenhexamid residues in plant commodities. A copy of the method has been sent to FDA for publication in the Pesticide Analytical Manual (PAM), Volume II, as a Roman numeral method. In the interim, it may be requested from: Calvin Furlow, PRRIB, 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 are no Codex or Mexican MRL tolerances established for fenhexamid and no Canadian MRL on pears..

VI. Conclusion

Therefore, the tolerance is established for residues of fenhexamid, (*N*-2,3-dichloro-4-hydroxyphenyl)-1-methyl cyclohexanecarboxamide), in or on pears at 15 ppm.

VII. 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–301075 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 January 22, 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 VII.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 the docket control number OPP–301075, 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 file format 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).

VIII. Regulatory Assessment Requirements

This final rule establishes a time limited tolerance under FFDCA section 408. 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require 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 FIFRA section 18 exemption under FFDCA section 408, such as the tolerance 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).

IX. 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: November 8, 2000.

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), (346a) and 371.

2. Section 180.553 is amended by revising paragraph (b) to read as follows:

§ 180.553 Fenhexamid; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the residues of the fungicide fenhexamid, (N-2,3-dichloro-4-hydroxyphenyl)-1-methyl cyclohexanecarboxamide), in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire on the dates specified in the following table:

Commodity	Parts per million	Expiration/ Revocation Date
Pears	15	12/31/02

* * * * *

[FR Doc 00–29770 Filed 11–20–00; 8:45 a.m.]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–6903–9]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of deletion of the Tenth Street Dump/Junkyard Superfund Site from the National Priorities List (NPL).

SUMMARY: The Environmental Protection Agency (EPA) Region 6 announces the deletion of the Tenth Street Dump/Junkyard Superfund Site (Site) located in Oklahoma City, Oklahoma from the National Priorities List (NPL). The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is codified at Appendix B to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 40 CFR Part 300. The EPA and the State of Oklahoma, through the Oklahoma Department of Environmental Quality (ODEQ), have determined that the Site poses no significant threat to public health or the environment and, therefore, no further response actions are appropriate. (Neither CERCLA-required five-year reviews nor operation and maintenance are considered further response action for the purpose of deletion.)

EFFECTIVE DATE: November 21, 2000.

FOR FURTHER INFORMATION CONTACT: Ms. Camille D. Hueni, Remedial Project Manager, 214–665–2231, United States Environmental Protection Agency, Region 6, 6SF–AP, 1445 Ross Avenue, Suite 1200, Dallas, Texas, 75202–2733. Information on the Site is available at the local information repository located at the Ralph Ellison Library, 2000 N.E. 23rd Street, Oklahoma City, Oklahoma 73111. Requests for comprehensive copies of documents should be formally directed to Mr. Donn Walters, Regional Superfund Information Management Team, EPA Region 6, SF–PO, 1445 Ross Avenue, Suite 1200, Dallas, Texas, 75202–2733.

SUPPLEMENTARY INFORMATION: The Site being deleted from the NPL is the Tenth Street Dump/Junkyard Superfund Site located in Oklahoma City, Oklahoma. A Notice of Intent to Delete for the Site was published on May 1, 2000 (65 FR 25292). The closing date for comments on the Notice of Intent to Delete was May 31, 2000. EPA received no comments and therefore no Responsiveness Summary was prepared.

The EPA identifies sites which appear to present a significant risk to public health, welfare, or the environment and maintains the NPL as the list of those sites. Deletion of a site from the NPL does not affect responsible party liability or impede EPA efforts to recover costs associated with response actions. Section 300.425(e)(3) of the NCP, 40 CFR 300.425(e)(3), states that Fund-financed actions may be taken at sites deleted from the NPL in the event that future conditions at the site warrant such action. Pursuant to CERCLA Section 105 and 40 CFR 300.425(e), the Site is hereby deleted from the NPL.

List of Subjects in 40 CFR Part 300

Environment protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental regulations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.