ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301043; FRL–6741–9]

RIN 2070–AB78

Clopyralid; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of clopyralid in or on peaches and nectarines. 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 peaches and nectarines. This regulation establishes a maximum permissible level for residues of clopyralid in these food commodities. The tolerances will expire and are revoked on December 31, 2002.

DATES: This regulation is effective September 27, 2000. Objections and requests for hearings, identified by docket control number OPP–301043 must be received by EPA on or before November 27, 2000.

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–301043 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/.

2.*In person*. The Agency has established an official record for this action under docket control number OPP–301043. 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, (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

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 tolerances for residues of the herbicide clopyralid, 3,6-dichloro-2-pyridinecarboxylic acid, in or on peaches and nectarines at 0.50 part per million (ppm). These tolerances will expire and are revoked on December 31, 2002. EPA will publish a document in the **Federal Register** to remove the revoked tolerances 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 Clopyralid on Peaches and Nectarines and FFDCA Tolerances

Plum pox virus was introduced to the United States in 1999 and has recently been found in Pennsylvania. This disease is a major threat to stone fruit production, and Delaware and New Jersey are requesting an emergency exemption for use of clopyralid since removal of broadleaf weeds that are alternate hosts for the virus, or are refugia for the green peach aphid, the vector of this virus, will enhance the effectiveness of imidacloprid which has already been exempted under section 18 of FIFRA for use to combat the aphid vector directly.

The registered alternative herbicides are not optimal for control of the weeds that clopyralid is being requested for. Most are for preemergence use on bare ground, and will not affect perennial weeds such as clover, Canada thistle, and asters. Some are non-selective and will kill the sod between tree rows, resulting in unacceptable erosion. Only 2,4-D is useful for some weeds, but for others, gives only partial control. While the use of imidacloprid to control the vectors is the major tool to contain or eradicate plum pox virus, an herbicide like clopyralid will enhance the effectiveness of imidacloprid by reducing the population of insects needing to be controlled, and the population of weeds that can serve as alternate hosts for the virus. EPA has authorized under FIFRA section 18 the use of clopyralid on peaches and nectarines for control of weeds that serve as alternate hosts for plum pox virus or are refugia for the green peach aphid in Delaware and New Jersey. After having reviewed the submission, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of clopyralid in or on peaches and nectarines. 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 these tolerances will expire and are 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 peaches and nectarines 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 these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether clopyralid meets EPA's registration requirements for use on peaches and nectarines or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of clopyralid by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Delaware and New Jersey 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 clopyralid, 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 clopyralid and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for residues of clopyralid in or on peaches and nectarines at 0.50 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. 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 endpoint. 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 intra species 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. The doses and toxicological endpoints selected and the LOC for margins of exposure for various exposure senarios are summarized in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CLOPYRALID 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 general population including females 13–50 years of age, infants and children	NOAEL = 75 mg/kg/day; UF = 100; Acute RfD = 0.75 mg/kg/day	FQPA SF = 3x; aPAD = acute RfD ÷ FQPA SF = 0.25 mg/kg/day	Developmental toxicity study in rats LOAEL = 250 mg/kg/day based on decreased weight gain and food consumption during days 6–9 of gestation. These effects in the maternal animal are believed to be due to one or a few doses given at the initiation of the dosing period (days 6–15).
Chronic Dietary all populations	NOAEL = 15 mg/kg/day; UF = 100; Chronic RfD = 0.15 mg/kg/day	FQPA SF = 3x; cPAD = chronic RfD ÷ FQPA SF = 0.05 mg/kg/day	Chronic Oral Toxicity /Carcinogenicity Study in Rats LOAEL = 150 mg/kg/day based on histopathologic findings in the stomach (epithelial hyperplasia and thickening of the limiting ridge).
Short-Term Dermal (1 to 7 days) (Residential)	none	none	none
Intermediate-Term Dermal (1 week to several months) (Residential)	none	none	none
Long-Term Dermal (several months to lifetime) (Residential)	none	none	none
Short-Term Inhalation (1 to 7 days) (Residential)	inhalation (or oral) study NOAEL = 75 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 300 (Residential)	Developmental study in rats LOAEL = 250 mg/kg/day based on decreased weight gain and food consumption during days 6–9 of gestation.
Intermediate-Term Inhalation (1 week to several months) (Residential)	inhalation (or oral) study NOAEL = 75 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 300 (Residential)	Developmental study in rats LOAEL = 250 mg/kg/day based on decreased weight gain and food consumption during days 6–9 of gestation.
Long-Term Inhalation (several months to lifetime) (Residential)	none	none	none
Cancer (oral, dermal, inhalation)	none	none	Clopyralid is negative for carcinogenicity in feeding studies in rats and mice at doses above the limit dose and has been classified as ''not likely'' to be a human carcinogen.

*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 180.431) for the residues of clopyralid, in or on a variety of raw agricultural commodities. Tolerances currently exist for residues of clopyralid on asparagus, barley, field corn, mint, oats, sugar beet tops, wheat, meat, milk and eggs. Additionally, time-limited tolerances for canola, cranberries and flax have been established. Risk assessments were conducted by EPA to assess dietary exposures from clopyralid 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 1–day or single exposure. 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 acute exposure assessments: 100% crop treated was assumed for all crops and residues were assumed to be at tolerance level.

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 CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: 100% crop treated was assumed for all crops and residues were assumed to be at tolerance level.

iii. *Cancer*. Clopyralid has been classified as ''not likely'' to be a human carcinogen. Therefore, an exposure assessment to address cancer risk is not required.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for clopyralid 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 clopyralid.

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 screening concentration in ground water (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 clopyralid they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the EECs of clopyralid for acute exposures are estimated to be 27 parts per billion (ppb) for surface water and 9.7 ppb for ground water. The EECs for chronic exposures are estimated to be 9 ppb for surface water and 9.7 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). Clopyralid is currently registered for use on the following residential non-dietary sites: turf and ornamentals. Applications can be made 1–2 times per year at rates up to 0.5 lb acid equivalent (ae) per acre. The current registered labels permit homeowners to mix/load/apply both liquid and granular formulations. The risk assessment was conducted using the following exposure assumptions: residential handlers may receive short-term dermal and inhalation exposure to clopyralid when mixing, loading and applying; adults and children may be exposed to clopyralid from dermal contact with residues when contacting foliage during post-application activities; and toddlers may also receive short-term oral exposure from hand-to-mouth ingestion during post-application activities.

No chemical-specific exposure or residue dissipation data for handler or post-application activities were submitted to the Agency in support of the registered lawn uses. Therefore, the Agency's Draft Standard Operating Procedures for Residential Exposure Assessments were used as the basis for all handler exposure calculations. The post-application risk assessment is based on generic assumptions as specified by the newly proposed Residential SOPs and recommended approaches by the Agency's Exposure Science Advisory Committee (ExpoSAC). Changes to the Residential SOPs have been proposed that alter the residential post-application scenario assumptions. The proposed assumptions are expected to better represent residential exposure and are still considered to be high-end, screening level assumptions. Agency management has authorized the use of the revised residential SOPs that were presented to the FIFRA SAP in September 1999. Therefore, the revised residential SOPs were used to calculate exposure estimates for the clorpyralid turf and ornamental uses.

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 clopyralid 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, clopyralid 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 clopyralid 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 the developmental study in rats, the maternal toxicity LOAEL is 250 mg/kg/ day based on death, reduced body weight gains, and reduced food consumption, and the maternal toxicity NOAEL is 75 mg/kg/day. The developmental toxicity NOAEL is greater than or equal to 250 mg/kg/day.

In the developmental toxicity study in rabbits, the maternal NOAEL is 110 mg/ kg/day based on death, clinical signs,

reduced body weight, and gastric lesions at the LOAEL of 250 mg/kg/day. The developmental NOAEL is also 110 mg/kg/day based on hydrocephalus (8 fetuses in 3 litters) at the LOAEL of 250 mg/kg/day.

iii. *Reproductive toxicity study*. In the 2-generation reproductive toxicity study in rats, the systemic toxicity NOAEL is 500 mg/kg/day. This endpoint is based on decreased body weights, body weight gains, and food consumption in the F_0 and F_1 males and females and slight focal hyperkeratotic changes in the gastric squamous mucosa of 1 of 30 F_0 males and 2 of 30 F_1 males at the LOAEL of 1,500 mg/kg/day. The reproductive toxicity NOAEL is 500 mg/kg bw/day. This endpoint is based on the decreased day 28 body weight of male pups of both litters of the F_1 generation and the increased relative liver weight of F_{1a} pups (both sexes) and F1b males of the F_1 generation at the LOAEL of 1,500 mg/kg/day.

iv. *Prenatal and postnatal sensitivity.* There is no evidence of qualitative or quantitative susceptibility following *in utero* exposure to rats or rabbits in the prenatal developmental studies or in the offspring following pre/postnatal exposure in the two generation rat reproduction toxicity study.

v. *Conclusion*. The FQPA 10x Safety Factor was reduced to 3x. This reduction was made because there is no quantitative or qualitative evidence of increased susceptibility following *in utero* exposure to rats and rabbits and/or following prenatal/postnatal exposure to rats. Additionally, the dietary (food and drinking water) and non-occupational exposure assessments will not underestimate the potential exposures for infants, children, and/or women of childbearing age. However, there was neuropathology in fetuses (hydrocephalus) in the rabbit developmental study. This study was considered a ''weak trigger'' for the requirement of a developmental neurotoxicity study. Therefore, the FQPA Safety Factor is 3x.

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 USEPA Office of Water are used to calculate DWLOCs: 2L/70 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 groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to clopyralid 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 clopyralid on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to clopyralid will occupy 8% of the aPAD for the U.S. population, 5% of the aPAD for females 13 years and older, 9% of the aPAD for all infants less than 1 year old (the infant subpopulation at greatest exposure) and 13% of the aPAD for children 1–6 years old (the children subpopulation at greatest exposure). In addition, despite the potential for acute dietary exposure to clopyralid in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of clopyralid in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CLORPYRALID

Population subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Acute DWLOC (ppb)
U.S. Population	0.25	8%	27	9.7	8100
Females, 13 years & older	0.25	5%	27	9.7	7100
All Infants (less than 1 year)	0.25	9%	27	9.7	2300
Children (1–6 years old)	0.25	13%	27	9.7	2200

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to clopyralid from food will utilize 14% of the cPAD for the U.S. population, 10% of the cPAD for all infants less than 1 year old (the infant subpopulation at greatest exposure) and 34% of the aPAD for children 1–6 years old (the children's subpopulation at greatest exposure). Though there are residential uses for clopyralid, based on the use pattern, chronic residential exposure is not expected. In addition, despite the potential for chronic dietary exposure to clopyralid in drinking water, after calculating the DWLOCs and comparing them to conservative model EECs of clopyralid in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.— AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CLOPYRALID

Population subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface water EEC (ppb)	Ground water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.05	14%	9	9.7	1500
Children, 1–6 years old	0.05	34	9	9.7	330
All Infants, less than 1 year old	0.05	10	9	9.7	450

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). Clopyralid is currently registered for use(s) that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for clopyralid. A short-term aggregate risk assessment was conducted for adults because there is potential for inhalation exposure to the residential handler. In addition, a short-term risk assessment was conducted for infants and children because of the potential for residential post-application oral exposure. Since no short-term dermal endpoint was identified, even though there is potential for short-term dermal exposures, no short-term dermal aggregate risk assessment was conducted.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 10,000 for inhalation exposure for adults, and 2,300 for children 1–6 years old and 2,400 for all infants less than 1 year old for post-application oral exposure. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of clopyralid in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as is shown in the following Table 4:

TABLE 4. — AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO CLOPYRALID

Population Subgroup	Aggregate MOE (food + residential)	Aggregate level of concern (LOC)	Surface water EEC (ppb)	Ground water EEC (ppb)	Short-Term DWLOC (ppb)
U. S. Population	10,000	300	9	9.7	8500
Children (1–6 years)	3,100	300	9	9.7	2300
All Infants (less than 1 year)	6,200	300	9	9.7	2400

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). Intermediate-term exposure is considered to be exposures that last for 1 week to several months. Though clopyralid is registered for use on turf and ornamentals, only 1–2 applications can be made. Therefore, intermediate-term exposure is not expected. Therefore, the short-term aggregate risk estimate discussed above, is considered protective of the aggregate exposure from non-dietary, non-occupational uses.

5. *Aggregate cancer risk for U.S. population*. Clopyralid has been classified as ''not likely'' to be a human carcinogen. Therefore, an aggregate risk assessment to address cancer risk is not required.

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 clopyralid residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate analytical method is available for enforcement of the proposed time-limited tolerance for peaches and nectarines. This method (ACR 79.5, Dow Chemical) is a Gas Chromatography method using a Hall electrolytic conductivity detector. The method has been validated for use on wheat and barley and has been submitted to FDA for publication in PAM II. The method 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, Canadian, or Mexican Maximum Residue Limits (MRL) for clopyralid on peaches or nectarines. International harmonization is therefore not an issue for these section 18 requests.

C. Conditions

No more than 0.375 lb clopyralid can be applied per acre per year. A 60–day preharvest interval (PHI) will be observed.

VI. Conclusion

Therefore, the tolerances are established for residues of clopyralid, 3,6-dichloro-2-pyridinecarboxylic acid, in or on peaches and nectarines at 0.50 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–-301043 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 November 27, 2000.

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–301043, 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 time limited tolerances 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 tolerances 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: September 8, 2000

Peter Caulkins,

Acting 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 180.431 is amended by alphabetically adding commodities to the table in paragraph (b) to read as follows:

§ 180.431 Clopyralid; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ revocation date
* *	*	* *
Nectarine	0.50	12/31/02
Peach	0.50	12/31/02

* * * * *

[FR Doc. 00–24320 Filed 9–26–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301041; FRL–6741–3]

RIN 2070–AB78

Diflubenzuron; Pesticide Tolerance Technical Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: EPA issued a final rule in the **Federal Register** of September 29, 1999, to establish a time–limited tolerance for diflubenzuron. This document is being issued to correct the expiration date for this tolerance, which was incorrectly given as March 31, 2000.

DATES: This technical correction is effective September 29, 1999.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit II. of the **SUPPLEMENTARY INFORMATION** To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–301041 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrea Conrath, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9356; e–mail address: beard.andrea@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

The Agency included in the final rule a list of those who may be potentially affected by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. 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/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301041. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis 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.

III. What Does this Technical Correction Do?

A time–limited tolerance for diflubenzuron on pears was published in the **Federal Register** on September 29, 1999 (64 FR 52450) (FRL–6382–1). This correction will change the expiration date for the tolerance to March 31, 2001. The document originally published with this date given in the body of the text. However, the table at the end of the document incorrectly listed the expiration date as March 31, 2000. This document corrects that error.