system regardless of whether that verification standard concentration is within ± 50% of sample response. If GC/MS analysis confirms the initial contaminant detection, report results determined from the initial analysis.

* * * * *

(11) Method Defined Quality Control. As appropriate to the method's requirements, perform analysis of Laboratory Fortified Blanks and Laboratory Performance Checks as specified in the method. Each method specifies acceptance criteria for these quality control checks.

[FR Doc. 01–59 Filed 1–10–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301099; FRL–6762–5]

RIN 2070–AB78

Clopyralid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends tolerances for residues of clopyralid (3,6-dichloro-2-pyridinecarboxylic acid) in or on sugar beet roots and sugar beet tops. In addition, this regulation establishes a tolerance for sugar beet molasses. Finally, the established tolerances for barley forage and milled fractions of barley, oats and wheat are being added back to the tolerance expression for clopyralid after being inadvertently deleted. Dow AgroSciences LLC requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective January 11, 2001. Objections and requests for hearings, identified by docket control number OPP–301099, must be received by EPA on or before March 12, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301099 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–6224; and e-mail address: miller.joanne@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'', ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. 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–301099. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of February 9, 1999 (64 FR 6351) (FRL–6058–3), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP 8F3600) for tolerance by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. This notice included a summary of the petition prepared by Dow AgroSciences LLC, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.431 be amended by establishing tolerances for residues of the herbicide clopyralid (3,6-dichloro-2-pyridinecarboxylic acid) in or on sugar beet roots at 2.0 parts per million (ppm), sugar beet tops at 3.0 ppm, and sugar beet molasses at 16.0 ppm.

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

exposure to the pesticide chemical residue....''

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of clopyralid (3,6-dichloro-2-pyridinecarboxylic acid) on sugar beet roots at 2.0 ppm, sugar beet tops at 3.0 ppm, and sugar beet molasses at 10.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

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

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity in mice	NOAEL = 2,000 mg/kg/day in both sexes; LOAEL = 5,000 mg/kg/day in both sexes based on decreased body weight in both sexes.
870.3200	21/28–Day dermal toxicity in rabbits	NOAEL ≥1,000 mg/kg/day for both sexes.
870.3250	90–Day dermal toxicity in rats	NA[1]
870.3465	90–Day inhalation toxicity in rats	NA
870.3700a	Prenatal developmental toxicity in rats	Maternal NOAEL = 75 mg/kg/day; LOAEL = 250 mg/kg/day based on mortality, reduced body weight gains and reduced food consumption; Developmental NOAEL ≥250 mg/kg/day
870.3700b	Prenatal developmental toxicity in rabbits	Maternal NOAEL = 110 mg/kg/day; LOAEL = 250 mg /kg/day based on mortality, clinical signs, decreased body weight gains, and lesions of the gastric mucosa; Developmental NOAEL = 110 mg/kg/day; LOAEL = 250 mg/kg/day based on decreased fetal body weight and hydrocephalus
870.3800	Reproduction and fertility effects in rats	Parental/Systemic NOAEL = 500 mg/kg/day for males and females; LOAEL = 1,500 mg/kg/day for males and females based on decreased body weights, decreased weight gain, and decreased food consumption in both sexes and slight focal hyperkeratotic changes in gastric squamous mucosa in males; Reproductive/Offspring NOAEL = 500 mg/kg/day for males and females; LOAEL = 1,500 mg/kg/day for males and females based on reduced pup weights in males and increased relative liver weight in pups of both sexes.
870.4100b	Chronic toxicity in dogs	NOAEL = 100 mg/kg/day in males and females. LOAEL = 320 mg/kg/day based upon reduction in hematological parameters in both sexes, increased absolute liver weight in males, and vacuolated adrenal cortical cells in females.
870.4300	Combined Chronic Toxicity/Carcinogenicity in rats	NOAEL = 15 mg/kg/day in males and females; LOAEL = 150 mg/kg/day based on epithelial hyperplasia and thickening of the limiting ridge of the stomach in both sexes. No evidence of carcinogenicity
870.4200b	Carcinogenicity in mice	NOAEL = 500 mg/kg/day in males and ≥2,000 mg/kg/day in females; LOAEL = 2,000 mg/kg/day in males based on decreased body weight, body weight gains, and food efficiency no evidence of carcinogenicity.
870.5300	*in vitro* and *in vivo* host mediated assay in bacteria	No evidence of induced mutant colonies over background in *Salmonella*strains TA 1,530 and G–46 and *Saccharomyces*strain D–3
870.5385	bone marrow chromosome aberrations assay	There was no significant increase in the frequency of chromosome aberrations in bone marrow at any dose tested.
870.5550	*in vitro* unscheduled DNA synthesis assay	There was no evidence of unscheduled DNA synthesis in initial or supplementary assays.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.5450	dominant lethal assay in rats.	No evidence of treatment related resorptions up to 400 mg/kg/day for 5 days.
870.6200a	Acute neurotoxicity screening battery in rats	NA
870.6200b	Subchronic neurotoxicity screening battery in rats	NA
870.6300	Developmental neurotoxicity in rats	NA
870.7485	Metabolism in rats	Rapidly absorbed and excreted mainly in the urine. Parent compound only is detected in the excreta.
870.7600	Dermal penetration	NA

[1]Not Applicable

B. Toxicological Endpoints

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

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

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

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 clopyralid used for human risk assessment is shown in the following Table 2:

TABLE 2.—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 infants and children	NOAEL = 75 mg ai/kg/day; UF = 100; Acute RfD = 0.75 mg ai/ kg/day	FQPA SF = 3X; aPAD = acute RfD/FQPA SF = 0.25 mg/kg/day	Developmental Toxicity Study - rat; Maternal LOAEL = 250 mg ai/kg/day based on decreased weight gain during gestation days 6–9.
Chronic Dietary all populations	NOAEL= 15 mg ai/kg/day; UF = 100; Chronic RfD = 0.15 mg/kg/day	FQPA SF = 3X; cPAD = chronic RfD/FQPA SF = 0.05 mg/kg/day	2–Year Chronic Toxicity/Carcinogenicity Study - rat; LOAEL = 150 mg ai/kg/day based on increased epithelial hyperplasia and thickening of the limiting ridge of the stomach in both sexes.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CLOPYRALID FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Short-Term (1–7 days) and Intermediate-Term (1 week - several months) Dermal (Occupational/Residential).	none	No systemic toxicity was seen at the limit dose (1,000 mg/kg/day) in the 21–day dermal toxicity study in rabbits. This risk assessment is not required.	NA
Short-Term (1–7 days) and Intermediate-Term (1 week - several months) Inhalation (Occupational/Residential)	NOAEL= 75 mg ai/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational); LOC for MOE = 300 (Residential)	Developmental Toxicity Study - rat; Maternal LOAEL = 250 mg ai/kg/day based on decreased body weight gain
Cancer (oral, dermal, inhalation)	''not likely''	NA	Acceptable oral rat and mouse carcinogenicity studies; no evidence of carcinogenic or mutagenic potential.

UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic), RfD = reference dose, MOE = margin of exposure, LOC = level of concern.
*The reference to the FQPA Safety Factor refers to any additional safety factor retained of concerns unique to the FQPA.

C. 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. Risk assessments were conducted by EPA to assess dietary exposures from clopyralid (3,6-dichloro-2-pyridinecarboxylic acid) 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. 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: For all commodities, 100% crop treated was assumed and those residues will be at the level of the tolerance (with one exception: refined sugar from sugar-beet). The above assumptions result in an overestimate of human dietary exposure. All Section 18 tolerances (canola, cranberries, flax seed, peaches, and nectarines) are included in this dietary risk assessment. With the exception of sugar beets, default processing factors were used for processed commodities. The empirical processing factor of 0.1X was used for sugar-beet representing the 10-fold reduction in residues for refined sugar. The aPAD for the U.S. population is 0.25 mg/kg/day. For acute dietary risk estimates, the level of concern is >100% aPAD. The population subgroup with the highest dietary exposure from food is children 1–6 years. The percentage of dietary exposure for this subgroup is 13% of the aPAD. The acute dietary risk estimates from residues in food which result from the established and proposed uses of clopyralid are below the level of concern for the U.S. population and all population subgroups.

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: For all commodities, 100% crop treated was assumed and those residues will be at the level of the tolerance (with one exception: refined sugar from sugar-beet). The empirical processing factor of 0.1X was used for sugar-beet representing the 10-fold reduction in residues for refined sugar. The cPAD for the general U.S. population and all subgroups is 0.05 mg/kg/day. For chronic dietary risk estimates, the Agency's level of concern is greater than 100% of the cPAD. The subgroup with the highest chronic dietary exposure from food is children 1–6 years. The percentage of dietary exposure for this subgroup is 34% of the cPAD. The chronic dietary risk estimates from residues in food resulting from the established and proposed uses of clopyralid are below the Agency's level of concern for the U.S. population and all population subgroups.

iii. *Cancer.* The Agency concluded that clopyralid was negative for carcinogenic potential in mice and rats and classified clopyralid as ''not likely'' to be a human carcinogen. Therefore, a cancer dietary exposure analysis was not performed.

iv. *Anticipated residue and percent crop treated information.* Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

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 SCI-GROW, which predicts pesticide concentrations in groundwater. 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 estimated environmental concentrations (EECs) of clopyralid for acute exposures are estimated to be 27.0 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, (based on a 56–day concentration of 27 ppb and a 3x adjustment factor allowed by Agency policy for 56–day GENEEC values) 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 (including golf courses). The risk assessment was conducted using the following residential exposure assumptions: the 75 mg/kg/day NOAEL was used in the inhalation, short-term, and intermediate-term hand-to-mouth, and episodic granular ingestion risk assessments of the residential exposure. As no dermal endpoint was selected, a dermal risk assessment was not required for residential exposure. For residential oral and inhalation risk assessments, the target margin of exposure (MOE) was 300, which incorporates the FQPA Safety Factor of 3x. MOEs calculated for residential handler's inhalation exposure and children's oral exposures were well above the target of 300; and therefore, do not exceed the Agency's level of concern.

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).

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity*. No increased quantitative or qualitative susceptibility was seen following pre- and/or post-natal exposures. In rabbit and rat developmental toxicity studies, the effects seen in fetuses are at dose levels equal to or greater than doses where maternal toxicity is seen. In a 2-generation reproductive toxicity study in rats, the effects seen in offspring were at dose levels equal to or greater than doses where parental toxicity is seen.

3. *Conclusion*. EPA determined that an additional factor to protect infants and children was appropriate because of a data gap for a developmental neurotoxicity study in rats. This study was required due to the concern for malformations (hydrocephalus) seen in the prenatal developmental toxicity study in rabbits; EPA decided on an additional factor of 3 rather than the statutory default factor of 10 because the existing toxicology database, which is complete except for the newly required developmental neurotoxicity study, revealed no quantitative or qualitative evidence of increased susceptibility following *in utero* exposure to rats and rabbits and/or following prenatal/ postnatal exposure to rats; and dietary (food and drinking water) and residential exposure assessments will not underestimate the potential exposures for infants, children, and/or women of childbearing age from the use of clopyralid.

E. 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 + residential 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 the pesticide 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 residues of the pesticide in 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 13–50 years, 9% of the aPAD for all infants <1 year and 13% of the aPAD for children between 1 and 6 years old. In addition, there is potential for acute dietary exposure to clopyralid in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CLOPYRALID

Population Subgroup	aPAD (mg/kg)	%aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. Population	0.25	8	9	9.7	8,100
All infants (< 1 year)	0.25	9	9	9.7	2,300
Children 1–6 years	0.25	13	9	9.7	2,200
Females 13–50 years	0.25	5	9	9.7	7,200

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, 11% of the cPAD for all infants < 1 year and 34% of the cPAD for children between 1 and 6 years old. Based on the use pattern, chronic residential exposure to residues of clopyralid is not expected. In addition, there is potential for chronic dietary exposure to clopyralid in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4.—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	1,500
All infants (< 1 year)	0.05	11	9	9.7	450
Children 1–6 years	0.05	34	9	9.7	330
Females 13–50 years	0.05	11	9	9.7	1,300

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 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.

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 (U.S. population, food and residential), 14,000 (females 13–50, food and residential) and 3,100 (children 1–6 years old, food and residential). 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 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 shown in the following Table 5:

TABLE 5.—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	8,500
Females 13–50	14,000	300	9	9.7	7,300
Children 1–6 years	3,100	300	9	9.7	2,300

4. *Intermediate-term risk*. Intermediate-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 intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for clopyralid.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 10,000 (U.S. Population, food only), 14,000 (females 13–50, food only) and 3,800 (children 1–6 years, food and residential). These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of clopyralid in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 6:

TABLE 6.—AGGREGATE AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO CLOPYRALID

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Inter-mediate-Term DWLOC (ppb)
U.S. Population	10,000	300	9	9.7	8,500
Females 13–50	14,000	300	9	9.7	7,300
Children 1–6 years	3,800	300	9	9.7	2,300

5. *Aggregate cancer risk for U.S. population*. The Agency concluded that clopyralid was negative for carcinogenicity potential in rats and mice and classified clopyralid as ''not likely'' to be a human carcinogen according to EPA Draft Guidelines for Carcinogen Risk Assessment. Therefore, a cancer risk assessment was not performed.

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.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate residue analytical method is available for enforcement of the proposed tolerances. This method, ACR 75.6, determines clopyralid as the methyl ester by gas chromatography using electron capture detection. This method has been successfully validated by the Biological and Economic Analysis Division's (BEAD) Analytical Chemistry Branch and has been published in FDA's Pesticide Analytical Manual, Vol-II (PAM II).

An adequate residue analytical method is also available for the enforcement of the proposed tolerance on animal commodities. This method, ACR 86.1, determines clopyralid as the methyl ester by gas chromatography using electron capture detection. This method has been successfully validated by BEAD's Analytical Chemistry Branch and has been published in FDA's Pesticide Analytical Manual, Vol-II (PAM II).

B. International Residue Limits

There are no Codex or Mexican maximum residue limits (MRLs). Canada has set a maximum residue limit of 2.0 ppm for barley, oats, and wheat, and 7.0 ppm for the milled fractions of barley, oats, and wheat (excluding flour).

C. Conditions

A revised label is needed to specify (1) a 48–hour restricted entry interval, and (2) whether plantback intervals for crops not listed in the crop rotation table will be 10.5 months or whether rotation to crops not listed will be prohibited. As a condition of registration, the registrant also needs to submit a developmental neurotoxicity study (870.6300) because neuropathology or central nervous system malformations were seen in the rabbit developmental toxicity study.

V. Conclusion

Therefore, tolerances are amended for residues of clopyralid (3,6-dichloro-2-pyridinecarboxylic acid), in or on sugar beet roots at 2.0 ppm and sugar beet tops at 3.0. In addition, a tolerance is established for residues of clopyralid in or on sugar beet molasses at 10 ppm. Finally, the established tolerances for barley forage at 9 ppm and milled fractions (except flour) of barley, oats and wheat at 12 ppm are being added back to the tolerance expression for clopyralid after being inadvertently deleted.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to

reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301099 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 March 12, 2001.

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

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

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

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

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

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301099, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review*(58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any 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 petition under FFDCA section 408(d), 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).

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: December 26, 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), 346(a) and 371.

2. Section 180.431 is amended by removing the entries for ''sugar beet roots'' and ''sugar beet tops'' and alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.431 Clopyralid; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Barley, forage	9.0
* * * * *	
Barley, milled fractions (except flour)	12
* * * * *	
Beet, sugar, molasses	10
Beet, sugar, roots	2.0
Beet, sugar, tops	3.0
* * * * *	
Oats, milled fractions (except flour)	12
* * * * *	
Wheat, milled fractions (except flour)	12

* * * * *

[FR Doc. 01–745 Filed 1–10–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 435

[HCFA–2086–F]

RIN 0938–AJ96

Medicaid Program; Change in Application of Federal Financial Participation Limits

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule changes the current requirement that limits on Federal Financial Participation (FFP) must be applied before States use less restrictive income methodologies than those used by related cash assistance programs in determining eligibility for Medicaid. This change was originally published as a proposed rule on October 31, 2000 (65 FR 64919).

This regulatory change is necessary because the current regulatory interpretation of how the FFP limits apply to income methodologies under section 1902(r)(2) of the Social Security Act (the Act) unnecessarily restricts States' ability to take advantage of the authority to use less restrictive income methodologies under that section of the statute. While the enactment of section 1902(r)(2) of the Act could be read in the limited manner embodied in current regulations the statute does not require such a reading, and subsequent State experience with implementing section 1902(r)(2)of the Act calls into question the current regulation's approach.

EFFECTIVE DATE: These regulations are effective on March 12, 2001.

FOR FURTHER INFORMATION CONTACT: Roy Trudel, (410) 786–3417.

SUPPLEMENTARY INFORMATION: Generally, in determining financial eligibility of individuals for the Medicaid program, State agencies must apply the financial methodologies and requirements of the cash assistance program that is most closely categorically related to the individual's status. Our regulations at 42 CFR 435.601 set forth the requirements for State agencies applying less restrictive income and resource methodologies when determining Medicaid eligibility under the authority of section 1902(r)(2) of the Social Security Act (the Act). Current regulations at 42 CFR 435.1007 provide that when States use less restrictive income and resource methodologies under section 1902(r)(2), the limits on Federal Financial Participation (FFP) in section 1903(f) of the Act apply before application of any less restrictive income methodologies. We are amending that regulation to change this requirement so that the 133⅓ percent FFP limit contained in section 1903(f)(1) of the Social Security Act would apply after application of any less restrictive income methodologies under section 1902(r)(2) of the Act.

The adoption of this policy gives States additional flexibility in setting Medicaid eligibility requirements. Also, we believe adoption of this policy reflects the intent of Congress to move the Medicaid program away from cash assistance program rules, as evidenced by enactment of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, which severed the link between the Aid to Families with Dependent Children (AFDC) program and Medicaid.

I. Background

Section 2373(c) of the Deficit Reduction Act of 1984 (DRA) established a moratorium period beginning on October 1, 1981, during which the Secretary was prohibited from taking any compliance, disallowance, penalty, or other regulatory action against a State because a State's Medicaid plan included a standard or methodology for determining financial eligibility for the medically needy that the Secretary determined was less restrictive than the