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: August 21, 2002.

Debra Edwards,

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 180.447 is revised to read as follows:

§ 180.447 Imazethapyr; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide imazethapyr, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo- 1H-imidazol-2-yl]-5-ethyl-3-pyridine carboxylic acid, applied as its acid or ammonium salt, in or on the following raw agricultural commodities:

Commodity	
Legume vegetables	0.1
Soybeans	0.1

(2)Tolerances are established for the sum of the residues of the herbicide imazethapyr, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo- 1H-imidazol-2-yl]-5-ethyl-3-pyridine carboxylic acid; its metabolite CL 288511, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1-hydroxyethyl)-3-pyridine carboxylic acid; and its metabolite CL 182704, 5-[1-(beta-D-glucopyranosyloxy)ethyl]-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-3-pyridinecarboxylic acid, applied as its acid or ammonium salt, in or on the following commodities:

Commodity	Parts per million
Alfalfa, forage	3.0
Alfalfa, hay	3.0
Peanut	0.1
Rice, bran	1.2
Rice, grain	0.20
Rice, straw	0.15

(3) A tolerance is established for the sum of residues of the herbicide imazethapyr, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo- 1H-imidazol-2-yl]-5-ethyl-3-pyridine carboxylic acid, and its metabolite CL 288511, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1-hydroxyethyl)-3-pyridine carboxylic acid, applied as its acid or ammonium salt, in or on the following commodities:

Commodity	Parts per million
Cattle, meat byproducts	0.10
Corn, field, forage	0.1
Corn, field, grain	0.1
Corn, field, stover	0.1
Crayfish	0.10
Goat, meat byproducts	0.10
Hog, meat byproducts	0.10
Horse, meat byproducts	0.10
Sheep, meat byproducts	0.10

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

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n) of this chapter, are established for the sum of residues of the herbicide imazethapyr, 2- [4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-ethyl- 3-pyridine carboxylic acid, as its ammonium salt, and its metabolite, 2- [4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1- hydroxyethyl)-3-pyridine carboxylic acid, both free and conjugated, applied as its acid or ammonium salt, in or on the following raw agricultural commodities:

Commodity	Parts per million
Endive (escorole)	0.1
Lettuce, head	0.1
Lettuce, leaf	0.1

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

[FR Doc. 02–22093 Filed 8–28–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0220; FRL–7195–8]

Diflufenzopyr; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of diflufenzopyr in or on corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; and corn, sweet, stover at 0.05 part per million (ppm); corn, pop, grain and corn, pop, stover at 0.05 ppm; grass, forage at 22 ppm; and grass, hay at 7.0 ppm. This regulation also establishes time-limited tolerances for combined residues of diflufenzopyr in or on cattle, goat, hog, horse, and sheep meat at 0.60 ppm; cattle, goat, hog, horse, and sheep kidney at 4.0 ppm; cattle, goat, hog, horse, and sheep meat byproducts, except kidney at 0.50 ppm; cattle, goat, hog, horse, and sheep fat at 0.30 ppm; and milk at 3.0 ppm. The Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective August 29, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0220, must be received on or before October 28, 2002.

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 ID number OPP–2002–0220 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–3194; e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. 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 ID number OPP–2002–0220. 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 December 12, 2001 (66 FR 64257) (FRL–6812–7), and June 12, 2002 (67 FR 40292) (FRL–7181–2), EPA issued notices pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA of 1996 (Public Law 104–170), announcing the filing of a pesticide petition (PP 0E6185) by IR–4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. These notices included a summary of the petition prepared by BASF Corporation, the registrant. There were no comments received in response to the notices of filing.

The petition requested that 40 CFR 180.549 be amended by establishing tolerances for the combined residues of the herbicide diflufenzopyr in or on corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; and corn, sweet, stover at 0.05 ppm; corn, pop, grain, and corn, pop, stover at 0.05 ppm; grass, forage at 22 ppm; and grass, hay at 7.0 ppm. The petition was subsequently revised to request that 40 CFR 180.549 be amended by establishing time-limited tolerances for residues of the herbicide diflufenzopyr, 2-(1-(3,5- difluorophenylamino) carbonyl)hydrazono)ethyl)(-3-pyridinecarboxylic acid, its metabolites convertible to 8-methylpyrido[2,3-d]pyridazin-5(6H)-one, and free and acid-released 8-hydroxymethylpyrido[2,3-d] pyridazine-2,5(1H,6H)-dione, expressed as diflufenzopyr, in or on cattle, goat, hog, horse, and sheep meat at 0.60 ppm; cattle, goat, hog, horse, and sheep kidney at 4.0 ppm; cattle, goat, hog, horse, and sheep meat byproducts, except kidney at 0.50 ppm; cattle, goat, hog, horse, and sheep fat at 0.30 ppm; and milk at 3.0 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 November 26, 1997 (62 FR 62961) (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 these actions. 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 the combined residues of diflufenzopyr on corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; corn, sweet, stover at 0.05 ppm; corn, pop, grain; and corn, pop, stover at 0.05 ppm; grass, forage at 22 ppm; grass, hay at 7.0 ppm; cattle, goat, hog, horse, and sheep fat at 0.30 ppm; cattle, goat, hog, horse, and sheep kidney at 4.0 ppm; cattle, goat, hog, horse, and sheep meat byproducts, except kidney at 0.50 ppm; cattle, goat, hog, horse, and sheep meat at 0.60 ppm;, and milk at 3.0 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follow.

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 diflufenzopyr is discussed in Unit III.A. of the Final Rule on Diflufenzopyr Pesticide Tolerance published in the **Federal Register** of January 28, 1999 (64 FR 4301) (FRL–6053–8).

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 diflufenzopyr used for human risk assessment is shown in the following Table 1:

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13–50 years of age)	NOAEL = 100 milligrams/kilogram/day (mg/kg/day) UF = 100 Acute RfD = 1.0 mg/kg/day	FQPA SF = 1X aPAD = acute RfD FQPA SF = 1.0 mg/kg/day	Rabbit Developmental LOAEL = 300 mg/kg/day based on extra ribs and other skeletal variations in the rabbit developmental study. These effects can occur from a single dose and females 13–50 are the population subgroup of concern. The developmental findings occurred at a level of severe maternal toxicity.
Acute dietary (general population including infants and children)	None	None	An appropriate endpoint attributable to a single exposure for this population subgroup was not identified in the oral toxicity studies including the maternal effects in rat and rabbit developmental studies.
Chronic dietary (all populations)	NOAEL = 26 mg/kg/day UF = 100 Chronic RfD = 0.26 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD FQPA SF = 0.26 mg/kg/day	52–Week feeding study in dogs LOAEL = 299 mg/kg/day based on compensated hemolytic anemia in both sexes of dogs
Short-term, and intermediate-term dermal (Residential)	None	None	No dermal or systemic toxicity was seen at 1,000 mg/kg/day in the 21–day dermal toxicity study in rabbits. Therefore, these risk assessments were not performed.
Long-term dermal (Residential)	None	None	The use pattern does not indicate a concern for potential residential dermal exposure. Therefore, this risk assessment was not performed.
Short-intermediate, and long-term inhalation (Residential)	None	None	The use pattern does not indicate a concern for potential residential inhalation exposure. Therefore, this risk assessment was not performed.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DIFLUFENZOPYR 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
Cancer (oral, dermal, inhalation)	None	None	In accordance with the 1996 Proposed Guidelines for Carcinogenicity Risk Assessments, diflufenzopyr was classified as ''Not Likely'' to be a human carcinogen. This classification is based on the lack of evidence of carcinogenicity in mice and rats when tested at doses that were judged to be adequate to assess carcinogenicity.

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have been established (40 CFR 180.549) for the combined residues of diflufenzopyr, in or on a variety of raw agricultural commodities. Time-limited tolerances are currently being established for cattle, goat, hog, horse, and sheep meat, kidney, liver, fat, and milk. Risk assessments were conducted by EPA to assess dietary exposures from diflufenzopyr 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 U.S. Department of Agriculture (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: An appropriate endpoint attributable to a single exposure for the general U.S. population (including infants and children) population subgroup was not identified in the oral toxicity studies including the maternal effects in rat and rabbit developmental studies. However, a Tier 1 acute dietary exposure assessment was performed for females 13–50 years old using recommended tolerance level residues (livestock) and total residues of concern (plants; parent and metabolites). Default DEEM™ concentration factors and 100% crop treated information were used for all commodities.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment, the DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The chronic dietary exposure analysis was performed for the general U.S. population and all population subgroups using recommended tolerance level residues (livestock) and total residues of concern (plants; parent and metabolites). Default DEEM™ concentration factors and 100% crop treated information were used for all commodities.

iii. *Cancer*. In accordance with the 1996 Proposed Guidelines for Carcinogenicity Risk Assessments, diflufenzopyr was classified as ''not likely'' to be a human carcinogen, therefore, a cancer exposure assessment was not performed.

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

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

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would 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 diflufenzopyr, they are further discussed in the aggregate risk sections in Unit III.E. Diflufenzopyr is not very stable and mobile. Based upon proposed uses, fate characteristics, and model predictions, the Agency does not expect diflufenzopyr to reach drinking water resources in significant quantities.

Based on the GENEEC and SCI-GROW models, the EECs of diflufenzopyr for

acute exposures are estimated to be 3.80 parts per billion (ppb) for surface water and 0.006 ppb for ground water. The EECs for chronic exposures are estimated to be 0.65 ppb for surface water and 0.006 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). Diflufenzopyr is not registered for use on any sites that would result in residential exposure, therefore, a residential exposure assessment was not performed.

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 diflufenzopyr 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, diflufenzopyr 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 diflufenzopyr 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*. Developmental NOAEL and the lowest observed adverse effect level (LOAEL) for both rats and rabbits occurred at either the same dose levels or were above the NOAELs and LOAELs for maternal toxicity. The NOAEL for pup effects in the 2-generation rat reproduction study occurred at dose levels above the NOAEL for parental findings. Based on these data, EPA determined that there was no evidence of increased sensitivity for infants and children.

3. *Conclusion*. There is a complete toxicity data base for diflufenzopyr and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be reduced to 1X. The FQPA safety factor is reduced because: (1) The toxicology data base is complete; (2) there is no indication of increased susceptibility of rats and rabbits fetuses to *in utero*, and/or postnatal exposure in the developmental and reproductive toxicity data; (3) unrefined (tier 1) dietary exposure estimates used in the risk assessment are protective since they will exaggerate dietary exposure estimates; (4) modeling data are used for ground and surface source drinking water exposure assessments resulting in estimates considered to be upper-bound concentrations; and (5) there are currently no registered residential uses for diflufenzopyr.

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 EPA 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 ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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, EPA 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*. An appropriate endpoint attributable to a single exposure for the general U.S. population (including infants and children) population subgroup was not identified. Therefore, the data do not indicate any adverse effect to the U.S. population subgroup as a result of acute dietary exposure. The acute dietary exposure assessment was performed for females 13–50 years old using tolerance level residues (livestock) and total residues of concern (plants; parent and metabolites). Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to diflufenzopyr will occupy 4% of the aPAD for females 13 years and older. In addition, there is potential for acute dietary exposure to diflufenzopyr 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 2:

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

Population Subgroup	aPAD (mg/kg)	%aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females (13–50 years old)	1.0	4	3.80	0.006	29,000

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to diflufenzopyr from food will utilize 9% of the cPAD for the U.S. population and all population subgroups. The most highly exposed population subgroup was children 1–6 years old utilizing 32% of the cPAD. There are no residential uses for diflufenzopyr that result in chronic residential exposure to diflufenzopyr. In addition, there is potential for chronic dietary exposure to diflufenzopyr in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water 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 DIFLUFENZOPYR

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.26	9	0.65	0.006	8,300
Females (13–50 years old)	0.26	5	0.65	0.006	7,400
Children (1–6 years old)	0.26	32	0.65	0.006	1,800
All infants (less than 1–year)	0.26	14	0.65	0.006	2,200

3. *Short-term and intermediate-term risk*. Short-term and intermediate-term aggregate exposures take into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short-term and intermediate-term aggregate risk assessments were not performed since there are no registered or proposed residential uses for diflufenzopyr. Therefore, short-term and intermediate-term exposure is not expected.

4. *Aggregate cancer risk for U.S. population*. In accordance with the 1996 Proposed Guidelines for Carcinogenicity Risk Assessments, diflufenzopyr was classified as ''not likely'' to be a human carcinogen. This classification is based on the lack of evidence of carcinogenicity in mice and rats when tested at doses that were judged to be adequate to assess carcinogenicity. The Agency concludes that pesticidal uses of diflufenzopyr are not likely to pose a carcinogenic risk to humans.

5. *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 diflufenzopyr residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

1. *Plants*. An adequate enforcement method is available for enforcement of the proposed tolerances for sweet corn and pop corn. The Agency has conducted a successful petition method validation (PMV) of method, and will be forwarded to the Food and Drug Administration (FDA) for inclusion in Pesticide Analytical Method Volume (PAM) Vol. II. The method may be requested from: Francis Griffith, Analytical Chemistry Branch, Environmental Science Center, Environmental Protection Agency, 701 Mapes Road, Fort George G. Mead, MD 20755–5350; telephone number: (410) 305–20905; e-mail address: griffith.francis@epa.gov.

2. *Livestock*. BASF Corporation has submitted an analytical method for livestock commodities, which has undergone independent laboratory validation.

B. International Residue Limits

There are currently no established Codex, Mexican maximum residue limits (MRLs) for residues of diflufenzopyr in/on plant or livestock commodities. A Canadian MRL of 0.05 ppm for residues of diflufenzopyr, expressed as the parent and metabolites convertible to M1, has been established for corn. No compatibility issues exist with regard to the existing and proposed U.S. tolerances.

C. Conditions

The registrant submitted a meat and milk magnitude of residue study in lactating dairy cows. Registration for use of diflufenzopyr on sweet corn, pop corn, forage, and hay grasses will be conditional pending the outcome of the Agency's review of the submitted study.

V. Conclusion

Therefore, the tolerances are established for combined residues of diflufenzopyr, 2-(1-[([3,5-difluorophenylamino] carbonyl)hydrazono]ethyl)-3-pyridinecarboxylic acid, and its metabolites convertible to 8-methylpyrido[2,3-d]pyridazin-5(6H)-one, expressed as diflufenzopyr, in or on corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; and corn, sweet, stover at 0.05 ppm; corn, pop, grain, and corn, pop, stover at 0.05 ppm; forage, grass at 22 ppm; and forage, hay at 7.0 ppm.

Time-limited tolerances are also established for combined residues of diflufenzopyr, 2-(1-[([3,5-difluorophenylamino] carbonyl)hydrazono]ethyl)-3-pyridinecarboxylic acid, its metabolites convertible to 8-methylpyrido[2,3-d]pyridazin-5(6H)-one, and free and acid-released 8-hydroxymethylpyrido[2,3-d]pyridazine-

2,5(1H,6H)-dione, expressed as diflufenzopyr, in or on cattle, goat, hog, horse, and sheep meat at 0.60 ppm; cattle, goat, hog, horse, and sheep kidney at 4.0 ppm; cattle, goat, hog, horse, and sheep meat byproducts, except kidney at 0.50 ppm; cattle, goat, hog, horse, and sheep fat at 0.30 ppm; and milk at 3.0 ppm.

VI. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0220 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 October 28, 2002.

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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your written request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall # 2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

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 ID number OPP–2002–0220, 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any

technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the 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). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

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

Dated: August 20, 2002.

Debra Edwards,

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 374.

2. Section 180.549 is amended by revising paragraph (a) to read as follows:

§ 180.549 Diflufenzopyr, tolerances for residues.

(a) *General*. Tolerances are established for combined residues of diflufenzopyr, 2-(1-[([3,5-difluorophenylamino]carbonyl) hydrazono]ethyl)-3-pyridinecarboxylic acid, and its metabolites convertible to 8-methylpyrido[2,3-d]pyridazin-5(6H)-one, expressed as diflufenzopyr, in or on the following raw agricultural commodities:

Commodity	Parts per million
Corn, field, forage	0.05
Corn, field, grain	0.05
Corn, field, stover	0.05
Corn, pop, grain	0.05
Corn, pop, stover	0.05
Corn, sweet, forage	0.05
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	0.05
Grass, forage	22.0
Grass, hay	7.0

(2) Time-limited tolerances are established for combined residues of diflufenzopyr, 2-(1-[([3,5-difluorophenylamino]carbonyl) hydrazono]ethyl)-3- pyridinecarboxylic acid, its metabolites convertible to 8-methylpyrido[2,3-d]pyridazin- 5(6H)-one, and free and acid-released 8-hydroxymethylpyrido[2,3-d]pyridazine-2,5(1H,6H)-dione, expressed as diflufenzopyr, in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/Revocation Date
Cattle, fat	0.30	7/31/05
Cattle, kidney	4.0	7/31/05

Commodity	Parts per million	Expiration/Revocation Date
Cattle, meat	0.60	7/31/05
Cattle, meat byproducts, except kidney	0.50	7/31/05
Goat, fat	0.30	7/31/05
Goat, kidney	4.0	7/31/05
Goat, meat	0.60	7/31/05
Goat, meat byproducts, except kidney	0.50	7/31/05
Hog, fat	0.30	7/31/05
Hog, kidney	4.0	7/31/05
Hog, meat	0.60	7/31/05
Hog, meat byproducts, except kidney	0.50	7/31/05
Horse, fat	0.30	7/31/05
Horse, kidney	4.0	7/31/05
Horse, meat	0.60	7/31/05
Horse, meat byproducts, except kidney	0.50	7/31/05
Milk	3.0	7/31/05
Sheep, fat	0.30	7/31/05
Sheep, kidney	4.0	7/31/05
Sheep, meat	0.60	7/31/05
Sheep, meat byproducts, except kidney	0.50	7/31/05

* * * * *

[FR Doc. 02–22092 Filed 8–28–02; 8:45 a.m.]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0144; FRL–7195–1]

Fosetyl-Al; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the fungicide, fosetyl-Al aluminum tris (*O*-ethylphosphonate) in or on bushberry subgroup, lingonberry, salal and juneberry at 40 parts per million (ppm); turnip tops at 40 ppm; turnip roots at 15 ppm; succulent pea at 0.3 ppm; and citrus fruit group at 5.0 ppm. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective August 29, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0144 must be received on or before October 28, 2002.

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 ID number OPP–2002–0144 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–7610; e-mail address: jackson.sidney@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–0144. 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