

*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). Because 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: February 24, 2000.

**Peter Caulkins,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

#### PART 180—[AMENDED]

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

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

2. Section 180.355 is amended in paragraph (a) by revising the introductory text and redesignating it as paragraph (a)(1), by revising the entry for "pea, succulent" in the table in newly designated paragraph (a)(1), by removing from the table in newly designated paragraph (a)(1) the entries for cattle, fat; cattle, meat byproducts; cattle, meat; egg; goats, fat; goats, mbyp; goats, meat; hogs, fat; hogs, mbyp; hogs, meat; milk; poultry, fat; poultry, meat byproducts; poultry, meat; sheep, fat; sheep, mbyp; and sheep, meat, and by adding new paragraph (a)(2). The additions and revision read as follows:

#### § 180.355 Bentazon; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the herbicide bentazon (3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one-2,2-dioxide) and its 6- and 8-hydroxy metabolites in or on the following food commodity:

Commodity	Parts per million
Pea, succulent .....	3.0

(2) Tolerances are established for the combined residues of the herbicide bentazon (3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one-2,2-dioxide) and its metabolite 2-amino-*N*-isopropyl benzamide (AIBA) in or on the following food commodities:

Commodity	Parts per million
Cattle, fat .....	0.05
Cattle, mbyp .....	0.05
Cattle, meat .....	0.05
Eggs .....	0.05
Goats, fat .....	0.05
Goats, mbyp .....	0.05

Commodity	Parts per million
Goats, meat .....	0.05
Hogs, fat .....	0.05
Hogs, mbyp .....	0.05
Hogs, meat .....	0.05
Milk .....	0.02
Poultry, fat .....	0.05
Poultry, mbyp .....	0.05
Poultry, meat .....	0.05
Sheep, fat .....	0.05
Sheep, mbyp .....	0.05
Sheep, meat .....	0.05

\* \* \* \*

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[OPP-300977; FRL-6492-3]

RIN 2070-AB78

#### Diclosulam; Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of diclosulam, *N*-(2,6-dichlorophenyl)-5-ethoxy-7-fluoro[1,2,4]triazolo[1,5-*c*]pyrimidine-2-sulfonamide, in or on soybean seed and peanut nutmeat. Dow AgroSciences 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 March 8, 2000. Objections and requests for hearings, identified by docket control number OPP-300977, must be received by EPA on or before May 8, 2000.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-300977 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703)

305-5697; and e-mail address: Tompkins.Jim@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	Crop production
	112	
	311	Food manufacturing
	32532	
		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" and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-300977. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI).

This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

### II. Background and Statutory Findings

In the **Federal Register** of November 20, 1998 (63 FR 64484) (FRL-6030-9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (PP) for a tolerance by Dow AgroSciences. This notice included a summary of the petition prepared by Dow AgroSciences, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the herbicide diclosulam, in or on soybean and peanut at 0.02 part per million (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 a tolerance for residues of diclosulam on soybean seed and peanut nutmeat at 0.020 ppm. EPA's assessment of the dietary 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 diclosulam are discussed in this unit.

In general, the toxicology studies conducted on diclosulam demonstrate that it has few or no biologically significant toxic effects at relatively low-dose levels in many animal studies. Diclosulam generally has low acute toxicity (Toxicity Category III) and is not a dermal sensitizer. The BF-564 (84.3% active ingredient (a.i.)) appeared to be slightly more irritating to the skin and eye than XDE-564 (97.6% a.i.). No significant treatment-related effects were noted in 21-day dermal studies in rabbits. Based on oral feeding studies, the primary target organs are the liver and kidney. In a subchronic rat feeding study, the primary target organ is the liver including increased relative organ weight, hepatocellular hypertrophy, and slight multifocal necrosis. Decreased body weight and kidney lesions were also noted. Liver effects were also noted in a subchronic dog study and included increased relative liver weight, centrilobular hepatocellular changes, and hepatocellular necrosis accompanied by elevated ALP, AST, and ALT. Other effects were decreased body weight, decreased food consumption, and renal changes in addition to hematological and clinical chemistry effects that were considered

secondary to the debilitated condition of the animals. In a chronic toxicity/ oncogenicity study in the rat, the kidney is identified as a target organ. Changes in clinical chemistry and urinalysis parameters (indicative of altered renal tubule function) included increased creatinine, decreased urine specific gravity, increased urine volume, and decreased urinary protein concentration; also, microscopic renal tubular pathology was noted. The kidney was also a target organ in a mouse carcinogenicity study. Among the observed kidney effects were reduced vacuolization in the tubular epithelium, lower absolute and relative kidney weights, and focal dilatation with hyperplasia of the epithelial lining in the cortical tubules. Diclosulam was classified as a "not likely human carcinogen" based on the lack of evidence of carcinogenicity in rats or mice fed diclosulam, and the lack of evidence of mutagenic activity. Based on the results of several subchronic, chronic, and developmental reproductive toxicity studies, there was no evidence of neurotoxicity. Diclosulam is not a developmental or reproductive toxicant and there was no evidence for increased susceptibility of rat or rabbit fetuses to *in utero* exposure or rat pups to postnatal exposure to diclosulam.

#### B. Toxicological Endpoints

1. *Acute toxicity.* In acute toxicology studies (rat acute neurotoxicity, rat developmental toxicity, and rabbit developmental toxicity) there were no acute effects observed due to a single dose. Therefore, no acute reference dose (RfD) was selected and an acute dietary risk assessment is not required.

2. *Short- and intermediate-term toxicity.* The toxicological endpoint for short- and intermediate-term inhalation risk assessments is a maternal/ developmental no observable adverse effect level (NOAEL) of 10 milligrams/ kilograms/day (mg/kg/day) based on the dose-dependent increased abortions, and decreased maternal body weight gain, food consumption, and fecal output in the rabbit oral developmental study. Because this study is an oral dosing study, route-to-route extrapolation is required. A margin of exposure (MOE) of 100 or greater is adequate for occupational exposure risk assessments. A short- and intermediate-term dermal risk assessment is not required, and no short- or intermediate-term dermal toxicity endpoints were established. In a short- and intermediate-term dermal toxicology study (21-day rabbit dermal toxicity

study), there was no systemic toxicity at the limit dose of 1,000 mg/kg/day.

3. *Chronic toxicity.* EPA has established a chronic RfD of 0.05 mg/kg/day NOAEL equals 5 mg/kg/day; Uncertainty Factor (UF) = 100 for use in assessing chronic dietary risk. This chronic RfD is based on the 2-year combined chronic feeding/ carcinogenicity study in rats, in which the following effects were observed at the lowest observable adverse effect level (LOAEL) of 100 mg/kg/day in both sexes: statistically significant decreases in body weight gain, changes in renal tubule and kidney function parameters, and increased incidence of male kidney pelvic epithelium hyperplasia.

4. *Carcinogenicity.* In accordance with the 1996 Cancer Risk Assessment Guidelines, the Agency classified diclosulam as a "not likely human carcinogen" based on the lack of evidence of carcinogenicity in mice or rats. Therefore, diclosulam is not expected to pose a cancer risk.

#### C. Exposures and Risks

1. *From food and feed uses.* Risk assessments were conducted by EPA to assess dietary exposures from as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. In acute toxicology studies (rat acute neurotoxicity, rat developmental toxicity, and rabbit developmental toxicity) there were no acute effects observed due to a single dose. Therefore, no acute risk is expected, and an acute risk assessment is inappropriate.

ii. *Chronic exposure and risk.* The Agency used the Dietary Exposure Evaluation Model (DEEM) software for conducting a chronic (non-cancer) dietary (food) risk analysis for residues in food. The chronic dietary risk analysis was based on the assumptions of tolerance level residues (0.020 ppm for peanut nutmeat and soybean seed), 100 percent of crop treated, and the chronic population-adjusted dose (PAD) of 0.05 mg/kg/day. The resulting dietary food exposures occupy <1% of the chronic PAD for all population subgroups. These results should be viewed as conservative (health protective) risk estimates. Refinements such as use of percent crop-treated information and/or anticipated residue values would yield even lower estimates of chronic dietary exposure from residues in food. In accordance with the 1996 Cancer Risk Assessment

Guidelines, EPA classified diclosulam as a "not likely human carcinogen" based on the lack of evidence of carcinogenicity in mice or rats. Thus, diclosulam is not expected to pose a cancer risk.

2. *From drinking water*—i. *Acute exposure and risk.* As explained above, diclosulam is not expected to pose an acute risk.

ii. *Chronic exposure and risk.* Drinking Water Levels of Comparison (DWLOCs) range from 490 to 1,700 µg/L for all population subgroups. DWLOCs were calculated based on the chronic PAD (0.05 mg/kg/day) and the chronic dietary (food only) exposure for each population subgroup. The estimated environmental concentrations (EECs) for assessing chronic aggregate dietary risk are 0.035 parts per billion (ppb) in ground water and 1.28 ppb in surface water. The chronic EECs are less than the Agency's level of comparison (the DWLOC value for each population subgroup) for diclosulam residues in drinking water as a contribution to chronic aggregate exposure.

3. *From non-dietary exposure.* There are no residential uses associated with diclosulam. Therefore, no non-dietary exposure due to residential use is expected.

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 diclosulam 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, diclosulam 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 diclosulam 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. Aggregate Risks and Determination of Safety for U.S. Population*

1. *Acute risk.* As explained above, diclosulam is not expected to pose an acute risk.

2. *Chronic risk.* Using the theoretical maximum residue contribution (TMRC) exposure assumptions described in this unit, EPA has concluded that aggregate exposure to diclosulam from food will utilize <1% of the PAD RfD for the U.S. population and all identified subpopulations. EPA generally has no concern for exposures below 100% of the PAD because the PAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for dietary exposure to diclosulam in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. However, there are not residential uses for diclosulam and risks from dietary exposures from residues in food and water are addressed by the acute and chronic risk assessments.

4. *Aggregate cancer risk for U.S. population.* As explained above, diclosulam is not expected to pose a cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to diclosulam residues.

#### *E. Aggregate Risks and Determination of Safety for Infants and Children*

1. *Safety factor for infants and children*—i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of diclosulam, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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 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. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* See Unit III.A. of this notice.

iii. *Reproductive toxicity study.* See Unit III.A. of this notice.

iv. *Prenatal and postnatal sensitivity.* Based on the available data, there is no indication of increased susceptibility of rats or rabbits to *in utero* and/or to postnatal exposure to diclosulam. In the prenatal developmental toxicity studies, there was no apparent developmental toxicity in rats or rabbits at or below the maternal toxicity NOAEL values (vide supra). In the prenatal rabbit developmental toxicity study, there were dose-dependent increased late (gestational date 21–27) abortions at or above 65 mg/kg/day. The Agency considers the dose-related increased abortions as an adverse fetal effect despite the fact that the abortions were probably related to maternal toxicity, the aborted fetuses were viable, and there was no increase in intra-uterine deaths (early or late resorptions). Both the maternal and developmental NOAEL/LOAEL were considered to be 10/65 mg/kg/day based on the dose-related increased abortions. There were other maternal effects, including decreased maternal body weight gain, food consumption, and fecal output; however, there were no other treatment-related fetal or developmental effects, including gravid uterine or fetal body weights, and gross, visceral, or skeletal changes. On the other hand, in the 2-generation rat reproduction study, the parental and developmental/ offspring systemic toxicity NOAEL/LOAEL were at or above the limit dose of 1,000 mg/kg/day.

v. *Conclusion.* The toxicological data base for diclosulam is adequate to support registration and tolerances. The Ames mutagenicity test is considered to be unacceptable because the highest

dose tested was not high enough. However, EPA has sufficient information concerning mutagenicity and has concluded that diclosulam is not a mutagen based on the Mouse Micronucleus Assay, CHO/HGPRT Forward Gene Mutation, Chromosomal Aberration Assay—Rat Lymphocytes tests. Also, both the acute neurotoxicity study (guideline) and the 1-year neurotoxicity study (non-guideline) are classified unacceptable pending the submission of additional information; however, these studies are not required to assess these tolerances or for registration of these uses. Exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Given the completeness of the toxicity and exposure data bases, and the lack of prenatal and postnatal sensitivity, EPA concluded that an additional safety factor to protect infants and children was not necessary and that a risk assessment using only the traditional safety factors would protect the safety of infants and children.

2. *Acute risk.* As explained above, diclosulam is not expected to pose an acute risk.

3. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to diclosulam from food will utilize <1% of the chronic PAD for infants and children. EPA generally has no concern for exposures below 100% of the chronic PAD because the PAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to diclosulam in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the PAD.

4. *Short- or intermediate-term risk.* As explained above, there are no residential uses for diclosulam and thus any short-term or intermediate term risks are adequately addressed by the chronic and acute assessments.

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

#### **IV. Other Considerations**

##### *A. Metabolism in Plants and Animals*

The nature (metabolism) of diclosulam residues in plants and livestock is adequately understood for the purposes of these tolerances. In all the plant and animal metabolism studies submitted, the residues of

concern were parent diclosulam only. The tolerances for soybean and peanut commodities are expressed in terms of diclosulam.

#### *B. Analytical Enforcement Methodology*

The petitioner has proposed Capillary Gas Chromatography/Mass Selective Detection Methods GRM 96.01, GRM 94.19, and GRM 94.19.S1 for the enforcement of tolerances in peanut and soybean. Method validation recoveries indicate that these methods adequately recover residues of diclosulam from peanut, soybean, and their processed commodities. The validated limit of quantitation (LOQ) is 0.01 ppm for all commodities and the limit of detection (LOD) was estimated to be 0.003 ppm for all matrices. Adequate independent method validation data have been submitted for this method.

#### *C. Magnitude of Residues*

The submitted soybean and peanut field trial data are adequate. The available residue data support the proposed tolerance at 0.020 ppm for residues of diclosulam in/on soybean seed. Residues were nondetectable (<0.003 ppm) in/on all 81 samples of soybeans treated at 1–1.5x. Diclosulam residues were also nondetectable (<0.003 ppm) in/on seed harvested from applications at exaggerated rates (5 3 and 8x). The processing data indicate that residues of diclosulam do not concentrate in soybean processed commodities. The proposed label includes a restriction against grazing treated areas or harvesting forage and hay from treated areas; therefore, tolerances for residues in/on soybean forage and hay are not required at this time.

In peanuts, the available residue data support the proposed tolerance at 0.020 ppm for residues of diclosulam in/on peanut nutmeats. Residues were nondetectable (<0.003 ppm) in/on all 22 samples of nutmeats treated at 1.4x. Diclosulam residues were also nondetectable (<0.003 ppm) in/on nutmeats harvested from applications at exaggerated rates (5 3 and 8x). The proposed label includes a restriction against grazing treated areas or harvesting forage and hay from treated areas. As all peanut nutmeat samples from the RAC field trials and exaggerated rate trials showed residues of diclosulam <0.003 ppm (<LOD), no tolerances for residues of diclosulam in peanut processed commodities are required. No tolerance for residues in/on peanut hay is needed since the proposed label includes a restriction against grazing treated areas or

harvesting forage and hay from treated areas.

#### *D. International Residue Limits*

There are no established or proposed Codex, Canadian or Mexican limits for residues of diclosulam in/on plant or animal commodities.

#### *E. Rotational Crop Restrictions*

The petitioner has proposed the following plantback restrictions for rotated crops: 4 months for wheat and barley; 6 months for oat and rye; 9 months for cotton, soybeans, and peanuts; 18 months for corn, rice, tobacco, and sorghum; and 30 months for all other crops due to phytotoxicity. EPA has determined that these plantback restrictions are adequate.

#### **V. Conclusion**

Therefore, the tolerance is established for residues of diclosulam in soybean seed and peanut nutmeat at 0.020 ppm.

#### **VI. Objections and Hearing Requests**

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-300977 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 May 8, 2000.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR

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

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, Ariel Rios Bldg., 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](mailto: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, Ariel Rios Bldg., 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, Ariel Rios Bldg., 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-300977, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

#### **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: February 29, 2000.

**James Jones,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

#### **PART 180 [AMENDED]**

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

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

2. Section 180.543 is added to read as follows:

#### **§ 180.543 Diclosulam; tolerances for residues.**

(a) *General.* Tolerances are established for residues of the herbicide diclosulam [N-(2,6-dichlorophenyl)-5-ethoxy-7-fluoro[1,2,4] triazolo[1,5-c]pyrimidine-2-sulfonamide] in or on the following raw agricultural commodities as follows:

Commodity	Parts per million
Peanut nutmeat .....	0.020
Soybean seed .....	0.020

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

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

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

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