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).

V. 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: July 18, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180–[AMENDED]

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

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

§ 180.449 [Amended]

2. In § 180.449, amend the table in paragraph (b) by revising the expiration/revocation date for ''basil'' from ''1/31/00'' to read ''7/31/01.''

[FR Doc. 00–19795 Filed 8–3–00; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301019; FRL–6596–3]

RIN 2070–AB78

Diflubenzuron; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of diflubenzuron and its metabolites in or on rangeland grass. Interregional Research Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 4, 2000. Objections and requests for hearings, identified by docket control number OPP–301019, must be received by EPA on or before October 3, 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–301019 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; and e-mail address: brothers.shaja@epamail.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/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301019. 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 April 5, 2000 (65 FR 17872) (FRL–6550–7), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a as amended by the FQPA (Public Law 104–170) announcing the filing of a pesticide petition (PP) for a tolerance by IR–4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. This notice included a summary of the petition prepared by Uniroyal Chemical Company, the registrant.

The petition requested that 40 CFR 180.377 be amended by establishing a tolerance for combined residues of the insecticide diflubenzuron, (N–[[4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide) and its metabolites, 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA), in or on rangeland grass at 6.0 parts 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 combined residues of diflubenzuron and its metabolites on rangeland grass at 6.0 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 diflubenzuron are discussed in Unit II.A. of the Final Rule on Diflubenzuron Pesticide Tolerance published in the **Federal Register** of April 19, 1999 (64 FR 19050) (FRL–6075–4).

B. Toxicological Endpoints

1. *Acute toxicity*. A toxicological endpoint for acute dietary exposure (1 day) was not established since 1 day single dose oral studies in rats and mice indicated only marginal effects on methemoglobin levels at a dose level of 10,000 milligrams/kilograms (mg/kg) of diflubenzuron.

2. *Short- and intermediate-term toxicity*. The toxicological endpoint for short-term occupational or residential exposure (1 to 7 days) is sulfhemoglobinemia observed in the 14-day subchronic oral study in mice dosed with technical grade diflubenzuron. The no observed adverse effect level (NOAEL) in this study was 40 mg/kg/day and the lowest observed adverse effect level (LOAEL) was 200 mg/kg/day.

The toxicological endpoint for intermediate-term occupational or residential exposure (1 week to several months) is methemoglobinemia observed in the 13-week subchronic feeding study in dogs. For the purpose of risk assessments, the NOAEL of 1.64 mg/kg/day in this study was considered to be 2 mg/kg/day so as to be consistent with the NOAEL of 2 mg/kg/day in the chronic study used to calculate the Reference Dose (RfD). The LOAEL in this study was 6.24 mg/kg/day.

Since an oral NOAEL was selected for a dermal endpoint, a dermal absorption factor of 0.5% was used for this risk assessment when converting dermal exposure to oral equivalents. Therefore, the dermal equivalent dose producing a NOAEL by the oral route is 400.0 mg/kg/day (i.e., 2.0 mg/kg/day divided by 0.005 = 400.0 mg/kg/day).

3. *Chronic toxicity*. EPA has established the RfD for diflubenzuron at 0.02 mg/kg/day. This RfD is based on the NOAEL of 2.0 mg/kg/day in the 52-week chronic oral study in dogs. An uncertainty factor of 100 (10X for interspecies extrapolation and 10X for intraspecies variation) was used to determine the chronic Reference Dose (cRfD) of 0.02 mg/kg/day. The chronic Population Adjusted Dose (cPAD) is equal to the cRfD divided by the FQPA Safety Factor. Since the FQPA Safety Factor was reduced to 1X, the cPAD is equal to the cRfD.

4. *Carcinogenicity*. Based on the available evidence, which included adequate carcinogenicity studies in rats and mice and a battery of negative mutagenicity studies, diflubenzuron *per se* has been classified as Group E (evidence of non-carcinogenicity for humans). However, p-chloroaniline (PCA), a metabolite of diflubenzuron, is classified as a Group B2 carcinogen (probable human carcinogen). See Unit II. B. in the Final Rule on Diflubenzuron Pesticide Tolerance published in the **Federal Register** of April 19, 1999 (64 FR 19050).

For the purpose of calculating dietary risk assessments from exposure through food to these metabolites of diflubenzuron, the following procedure was used:

i. P-chlorophenylurea (CPU) and p-chloroacetanilide (PCAA), additional metabolites of diflubenzuron that are closely related to PCA and for which there are no adequate carcinogenicity data available, was considered to be potentially carcinogenic and to have the same carcinogenic potency (Q_1*) as PCA.

ii. The sum of PCA, CPU, and PCAA residues in ingested food was used to estimate the dietary exposure of humans to the carcinogenic metabolites of diflubenzuron in food.

iii. In addition to ingested residues of these three metabolites, amounts of PCA, CPU, and/or PCAA formed *in vivo* following ingestion of diflubenzuron was also included when estimating the total exposure of humans to the

carcinogenic metabolites of diflubenzuron. The *in vivo* conversion of ingested diflubenzuron to PCA and/or CPU was estimated to be 2.0%, based on data in the rat metabolism study.

The Q_1* (estimated unit risk) for PCA, based upon spleen sarcoma rates in male rats, was calculated to be 6.38 x 10^{-2} (mg/kg/day) in human equivalents. It has been determined that PCAA does not occur in animal or plant tissues in significant amounts.

C. Exposure Assessment

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.377) for the combined residues of diflubenzuron and its metabolites, in or on rice grain, rice straw, citrus, artichokes, walnuts, mushrooms, cottonseed, soybeans, and associated livestock. For the dietary risk assessment, anticipated residue levels were calculated for livestock, citrus and mushroom commodities. Anticipated residue estimates for diflubenzuron were not calculated for other raw agricultural commodities. Percent crop treated (PCT) data were utilized where available.

Risk assessments were conducted by EPA to assess dietary exposures in food from diflubenzuron and its metabolites as follows:

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

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information to conduct a routine chronic dietary exposure analysis for diflubenzuron based on likely maximum PCT as follows: 1% rangeland grass, 3% cottonseed, 8% grapefruit, 3.1% mushrooms, 2% oranges, 4% tangerines, 1% soybean, and 5% cattle bolus. Other commodities were assumed to be 100% treated.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. The Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer–based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which diflubenzuron and its metabolites may be applied in a particular area.

i. *Acute exposure.* A risk assessment for acute dietary exposure (1 day) was not conducted. One day single dose oral studies in rats and mice indicated only marginal effects on methemoglobin levels at a dose level of 10,000 mg/kg of diflubenzuron.

ii. *Chronic exposure.* The RfD used for the chronic dietary analysis for diflubenzuron is 0.02 mg/kg bwt/day. The chronic Dietary Exposure Evaluation Model (DEEM) analysis used mean estimates of consumption (3-day average). Anticipated residues and PCT information for select commodities were used. Since EPA determined to reduce the 10X FQPA Safety factor to 1X, the cPAD and the cRfD are the same. The results of the analyses indicate that the chronic dietary risks from food associated with the existing and proposed uses of diflubenzuron and its metabolites do not exceed EPA's level of concern for the U.S. population or any population subgroup.

Cancer risk from consumption of PCA and related metabolites. The Agency has determined that there are three possible sources for dietary exposure to PCA and related compounds (CPU and PCAA) from food: residues in plants/fungi (mushrooms), residues in animal commodities (milk and liver) and *in vivo* conversion of diflubenzuron.

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

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

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOC) 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.

To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DEEM) was subtracted from the RfD to obtain the acceptable chronic (non-cancer) exposure to diflubenzuron in drinking water. To calculate the DWLOC for chronic exposures relative to a carcinogenic toxicity endpoint, the chronic (cancer) dietary food exposure was subtracted from the ratio of the negligible cancer risk to the Q* to obtain the maximum allowable chronic exposure to diflubenzuron in drinking water. DWLOCs were then calculated using default body weights and drinking water consumption figures.

EPA has calculated DWLOCs for chronic (non-cancer) dietary exposure to diflubenzuron in surface and ground water for the U.S. population and children (1-6 yrs). They are 700 and 200 parts per billion (ppb), respectively. For chronic (cancer) exposure to CPU in surface and ground water, the DWLOC is 0.30 ppb for the U.S. population.

Tier II PRZM-EXAM modeling using the index reservoir (IR) scenario and the percent crop area adjustment factor for the use of diflubenzuron on cotton and citrus was modeled. The concentration of diflubenzuron in drinking water in a Mississippi cotton index reservoir scenario adjusted for a percent crop area factor of 0.49 is not expected to exceed 1.66 µg/L for the 1 in 10-year annual peak (acute) concentration, 0.12 µg/L for the 1 in 10-year annual mean (chronic) concentration, and 0.06 µg/L for the 36-year average concentration. The concentration of CPU in drinking water from the same application on cotton is not expected to exceed 0.23 µg/L for the 36-year average concentration.

Based on the PRZM–EXAMS and SCI–GROW models, the EECs of diflubenzuron for chronic exposure are estimated to be 0.06 ppb for surface water and 0.0023 ppb for ground water.

3. *From non-dietary exposure*. Diflubenzuron is a restricted use pesticide and therefore not available for use by homeowners. However, non-agricultural uses of diflubenzuron may expose people in residential locations. Based on the low dermal absorption rate (0.5%), and the extremely low dermal and inhalation toxicity, exposure through these uses is expected to be insignificant.

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 diflubenzuron 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, diflubenzuron 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 diflubenzuron 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*. There is no risk from acute dietary exposure (1 day) to diflubenzuron as there is no toxic endpoint identified.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to diflubenzuron from food will utilize <1% of the cPAD for the U.S. population, for infants <1 year old, and children 1-6 years old. There are no residential uses for diflubenzuron that result in chronic residential exposure. In addition, despite the potential for chronic dietary exposure to diflubenzuron in drinking water, after calculating the DWLOCs and comparing them to conservative model EECs of diflubenzuron in surface water 0.06 ppb and ground water 0.0023 ppb. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Aggregate cancer risk for U.S. population*. For the U.S. population, cancer risk resulting from food exposure is 4.5×10^{-7}. The estimated 36-year average concentration (0.23 ppb) of CPU in surface water does not exceed EPA's level of concern (DWLOC) for CPU in drinking water (0.30 ppb) as a contribution to chronic (cancer) aggregate exposure. EPA has calculated that the cancer risk resulting from 0.23 ppb of CPU in drinking water is 4.2×10^{-7}. The aggregate cancer risk is thus 8.7×10^{-7} (4.5×10^{-7} for food + 4.2×10^{-7} for water).

4. *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 residues of diflubenzuron and its metabolites.

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

1. *Safety factor for infants and children in general*. In assessing the potential for additional sensitivity of infants and children to residues of diflubenzuron and its metabolites, 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.

2. *Developmental toxicity studies* —i. *Rats*. In the developmental study in rats, the maternal (systemic) NOAEL was 1,000.0 mg/kg/day highest dose tested (HDT). The developmental (fetal) NOAEL was 1,000.0 mg/kg/day, (HDT).

ii. *Rabbits*. In the developmental toxicity study in rabbits, the maternal (systemic) NOAEL was 1,000.0 mg/kg/day, HDT. The developmental (pup) NOAEL was 1,000.0 mg/kg/day, HDT.

iii. *Reproductive toxicity study*. In the 2-generation reproductive toxicity study in rats, the maternal (systemic) NOAEL was < 36 and < 42 mg/kg/day male and female, respectively. Lowest dose tested (LDT) based on hematological effects at all dose levels tested. The reproductive (pup) NOAEL was 427.0 mg/kg/day, based on decreases in the F–1 pup weight at the LOAEL of 2,454.0 mg/kg/day HDT.

iv. *Conclusion*. The toxicological data base for evaluating prenatal and postnatal toxicity for diflubenzuron is complete with respect to current data requirements. Based on the developmental and reproductive toxicity studies discussed above, there does not appear to be increased sensitivity to diflubenzuron for prenatal or postnatal effects. Based on the above, EPA concludes that reliable data support use of a 100-fold margin of exposure/uncertainty factor, rather than the 1,000-fold margin/factor, to protect infants and children.

3. *Acute risk*. There is no risk from acute dietary exposure (1 day) to diflubenzuron as there is no toxicological endpoint identified which could be attributable to a single dietary exposure. Therefore, a risk assessment for this exposure scenario was not conducted.

4. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to diflubenzuron from food will utilize < 1 % of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD 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 diflubenzuron in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

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 diflubenzuron residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate methods are available for the analysis of diflubenzuron and its metabolites in rice grain (0.01 ppm), rice straw (0.01 ppm) and water (0.001 ppm). Three enforcement methods for diflubenzuron are published in PAM, Vol. II as Methods I, II, and III. Method II is a GC/ECD method that can separately determine residues of diflubenzuron, CPU, and PCA in eggs, milk, and animal tissues. All three methods have undergone successful Agency validations and are acceptable for enforcement purposes.

B. International Residue Limits

There are no Codex proposals, Canadian, or Mexican limits for residues of diflubenzuron on rangeland grass. A compatibility issue is not relevant to the tolerance.

V. Conclusion

Therefore, the tolerance is established for combined residues of diflubenzuron and its metabolites, in or on rangeland grass at 6.0 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 control number OPP–301019 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 3, 2000.

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

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

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

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

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of

Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit 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–301019, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

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: July 17, 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 180.377 is amended by revising paragraph (a)(2), and in the table in paragraph (c) removing the entry for ''Grass, range''.

§ 180.377 Diflubenzuron; tolerances for residues.

(a) * * *

(2) Tolerances are established for the combined residues of the insecticide diflubenzuron (*N*–[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide) and its metabolites 4-chlorophenylurea and 4-chloroaniline in or on the following food commodities:

Commodity	Parts per million
Grass, rangeland	6.0

* * * * *

[FR Doc. 00–19794 Filed 8–3–00; 8:45 am]

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