Commodity	Parts per million
Cattle, fat	1 ppm
Cattle, mbyp	3.5 ppm
Cattle, meat	0.5 ppm
Cotton gin byproducts	7.0 ppm
Cotton, hulls	5.0 ppm
Cotton, undelinted seed	1.5 ppm
Eggs	0.05 ppm
Goats, fat	1 ppm
Goats, mbyp	3.5 ppm
Goats, meat	0.5 ppm
Hogs, fat	1 ppm
Hogs, mbyp	3.5 ppm
Hogs, meat	0.5 ppm
Horses, fat	1 ppm
Horses, mbyp	3.5 ppm
Horses, meat	0.5 ppm
Milk	0.1 ppm
Poultry, fat	0.05 ppm
Poultry, mbyp	0.3 ppm
Poultry, meat	0.05 ppm
Sheep, fat	1 ppm
Sheep, mbyp	3.5 ppm
Sheep, meat	0.5 ppm

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300660; FRL–5790–5]

RIN 2070–AB78

Diflubenzuron; Temporary Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary tolerance for residues of the insecticide diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and metabolites convertible to p-chloroaniline expressed as diflubenzuron on rice grain at 0.01 ppm. Uniroyal Chemical Company, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 requesting this temporary tolerance in association with an Experimental Use Permit (EUP) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

DATES: This regulation is effective May 13, 1998. Objections and requests for hearings must be received by EPA on or before July 13, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300660], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300660], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300660]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Paul Schroeder, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-6602, e-mail: schroeder.paul@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 25, 1998 (63 FR 9528) (FRL–5775–3), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP 6G4771) from Uniroyal Chemical Company, Inc., Bethany, CT proposing to amend 40 CFR part 180 by establishing a tolerance for residues of the insect growth regulator, diflubenzuron and metabolites convertible to p-chloroaniline, expressed as diflubenzuron in or on rice at 0.02 parts per million (ppm) and rice straw at 0.8 ppm. The notice included a summary of the petition prepared by Uniroyal Chemical Company, Inc., the registrant. In the **Federal Register** of March 9, 1998 (63 FR 11445) (FRL–5777-8), a clarification of the notice of filing was published explaining that Uniroyal had submitted two petitions, 6G4771, for the establishment of a temporary tolerance in or on rice at 0.01 ppm in association with a 3,000 acre EUP, and 8F4925, to amend 40 CFR 180.377 to include a tolerance for residues of the insect growth regulator, diflubenzuron and metabolites convertible to p-chloroaniline, expressed as diflubenzuron in or on rice at 0.02 parts per million (ppm) and rice straw at 0.8 ppm. There were no comments received in response to the notice of filing or the clarification.

I. Risk Assessment and Statutory Findings

EPA establishes maximum legal levels (tolerances) for pesticide residues on food under section 408 of FFDCA. EPA performs a number of analyses to determine the risk 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).

II. 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 residues of the insecticide diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and metabolites convertible to p-chloroaniline expressed as diflubenzuron on rice grain at 0.01, and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of the insecticide diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and metabolites convertible to p-chloroaniline expressed as diflubenzuron on rice grain at 0.01. 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 (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and metabolites convertible to p-chloroaniline expressed as diflubenzuron have been fully described in the Reregistration Eligibility Decision (RED) document (EPA 738-R-97-008, August 1997), a copy of which is in the public docket.

B. Toxicological Endpoints

1. *Acute toxicity*. A risk assessment for acute dietary exposure (1 day) is not necessary. One 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 (25% wettable powder formulation). Sulfhemoglobin levels and Heinz bodies were not affected.

2. *Short- and intermediate-term toxicity*. The toxicology 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 effect level (NOEL) in this study was 40 mg/kg/day and the lowest effect level (LEL) was 200 mg/kg/day.

The toxicology 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 NOEL of 1.64 mg/kg/day in this study should be considered to be 2 mg/kg/day so as to be consistent with the NOEL of 2 mg/kg/day in the chronic study used to calculate the RfD.

The LEL in this study was 6.24 mg/kg/day. There were no acceptable dermal absorption studies available. However, a dermal absorption rate was selected from an acceptable dermal absorption submitted to the Agency on June 25, 1996. From that study, a dermal absorption rate of 0.50% for exposures of 1 to 10 hours was determined for use in an occupational exposure assessment.

3. *Chronic toxicity*. The RfD was determined to be 0.02 mg/kg/day and is based on the NOEL of 2.0 mg/kg/day in the 52–week chronic oral study in dogs. Increases in methemoglobin and sulfhemoglobin were observed at the next higher dose level of 10.0 mg/kg/day. An uncertainty factor of 100 was applied to account for the interspecies extrapolation and intraspecies variability. Diflubenzuron has been reviewed by the FAO/WHO joint committee on pesticide residues and an Acceptable Daily Intake (ADI) of 0.02 mg/kg/day was established in 1985. The ADI was based upon the one-year oral toxicity study in dogs with a NOEL of 2.0 mg/kg/day. A safety factor of 100 was applied to account for the interspecies extrapolation and intraspecies variability.

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, was classified as a Group B2 carcinogen (probable human carcinogen). The classification for PCA was based on the results of a National Toxicology Program (NTP) study reported in July 1989 in which p-chloroaniline hydrochloride was administered by gavage to rats and mice for 2 years. In rats, clearly increased incidences of uncommon sarcomas (fibrosarcomas, hemangiosarcomas and/or osteosarcomas) of the spleen were observed in males. In females, two additional sarcomas of the spleen were also found. Pheochromocytomas of the adrenal gland may also have been associated with the test material in male and female rats. In mice, increased incidences of hepatocellular neoplasms in the liver and of hemangiosarcomas in the spleen and/or liver were observed in males. In females, no evidence of carcinogenic activity was observed. The results of several mutagenicity studies on PCA were also included in the same NTP report. PCA was mutagenic in Salmonella strains TA98 and TA100 with metabolic activation. Gene mutations were induced by PCA in cultured mouse lymphoma cells with and without metabolic activation. In cultured Chinese hamster ovary (CHO) cells, treatment with PCA produced significant increases in sister chromatid exchanges (SCEs) with and without metabolic activation. Chromosomal aberrations were also significantly increased in CHO cells in the presence of metabolic activation.

For the purpose of calculating dietary risk assessments, the following procedure was used:

a. 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, should be considered to be potentially carcinogenic and to have the same carcinogenic potency (Q1*) as PCA.

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

c. In addition to ingested residues of these three metabolites, amounts of PCA, CPU, and/or PCAA formed *in vivo* following ingestion of diflubenzuron should also be 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 Q1* (estimated unit risk) for PCA, based upon spleen sarcoma rates in male rats, was calculated to be 6.38 x 10^{-2} $(mg/kg/day)^{-1}$ in human equivalents.

Where no PCA, CPU, and/or PCAA are present, the toxicological endpoint for diflubenzuron *per se* should be used for risk assessments.

Regarding potential carcinogenic risks to humans resulting from dermal and/or inhalation exposures to PCA, CPU, and/or PCAA occurring during occupational or residential exposures to diflubenzuron, it has been determined that these risks are likely to be negligible since exposure to these metabolites is not anticipated. Only in the event that direct exposure to one or more of these metabolites of diflubenzuron is demonstrated would it be necessary to perform such risk assessments.

It has been determined that PCAA does not occur in animal or plant tissues in significant amounts.

5. *Special sensitivity to infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of diflubenzuron, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproductive toxicity study in the rat. Developmental toxicity studies are designed to evaluate adverse effects on the developing fetus resulting from maternal pesticide exposure during gestation. Reproductive toxicity studies provide information relating to pre- and post-natal effects from exposure to the pesticide, information on the reproductive capability of mating animals, and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional 10-fold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal 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 analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the no observed effect level in the animal study appropriate to the particular risk assessment. This 100-fold uncertainty (safety) factor/margin of exposure (safety) is designed to account for inter-species extrapolation and intra-species variability. EPA believes that reliable data support using the 100-fold margin/factor, rather than the 1,000-fold margin/factor, when EPA has a complete data base under existing guidelines, and when the severity of the effect in infants or children, the potency or unusual toxic properties of a compound, or the quality of the exposure data do not raise concerns regarding the adequacy of the standard margin/factor.

a. *Developmental toxicity studies*—i. *Rats*. In the developmental study in rats, the maternal (systemic) NOEL was 1,000.0 mg/kg/day [HDT]. The developmental (fetal) NOEL was 1,000.0 mg/kg/day, [HDT].

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

b. *Reproductive toxicity studies*. In the 2-generation reproductive toxicity study in rats, the maternal (systemic) NOEL was <36 males/<42 females mg/kg/day, [LDT] based on hematological effects at all dose levels tested. The reproductive (pup) NOEL was 427.0 mg/kg/day, based on decreases in the F-1 pup weight at the LEL of 2,454.0 mg/kg/day [HDT].

c. *Pre- and post-natal sensitivity*. The toxicological data base for evaluating pre- and post-natal toxicity for diflubenzuron is complete with respect to current data requirements. There is an ongoing review of these data with respect to the requirements of the Food Quality Protection Act. However, a preliminary decision, for purposes of this temporary tolerance, is that there is no extra sensitivity for pre- or post-natal effects and that there are reliable data to support use of a 100-fold margin of exposure/uncertainty factor, to protect infants and children.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.377) for residues of diflubenzuron *per se*, in or on citrus, artichokes, walnuts, mushrooms, cottonseed, soybean, and associated livestock commodities. Existing tolerances range from 0.05 ppm in/on soybeans to 6.0 ppm in/on artichokes. Tolerances of 0.05 ppm have also been established for residues of diflubenzuron in animal commodities.

For the dietary risk assessment, anticipated residues levels for were calculated in livestock commodities. Anticipated residue estimates for diflubenzuron were not calculated for raw agricultural commodities. Percent crop treated data were utilized where available.

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: (1) That the data used are reliable and provide a valid basis for showing the percentage of food derived from a crop that is likely to contain residues; (2) that the exposure estimate does not underestimate the exposure for any significant subpopulation and; (3) where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of these estimates of percent crop treated as required by section 408(b)(2)(F), EPA may require registrants to submit data on percent crop treated (PCT).

Dietary exposure estimates were based on the following percent crop treated estimates: grass/rangeland, 1%; cottonseed, 3%; soybean, 1%; cattle bolus, 5%. Other commodities were assumed to be 100 percent treated. The Agency believes that the three conditions listed above have been met. With respect to (1), EPA finds that the PCT information described above for diflubenzuron is reliable and has a valid basis. The Agency has utilized statistical data from public and proprietary sources, including DOANE, and checked these against data provided by the registrant. These are the best available sources for such information. Concerning (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 data available through national food consumption surveys, EPA does not have available information on the consumption of food bearing diflubenzuron in a particular area.

Risk assessments were conducted as follows:

a. *Acute exposure and risk*. A risk assessment for acute dietary exposure (1 day) is not necessary. 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 (25% wettable powder formulation). Sulfhemoglobin levels and Heinz bodies were not affected.

b. *Chronic exposure and risk*. A chronic dietary risk assessment is required for diflubenzuron. The RfD used for the chronic dietary analysis for diflubenzuron is 0.02 mg/kg bwt/day. The DRES analysis utilized anticipated residues and percent crop treated, where available. The proposed diflubenzuron tolerance result in a dietary exposure that is equivalent to the following percent of the RfD:

Subgroups	Diflubenzuron
U.S. population (48 states)	< 1%
Hispanics	< 1%
Non-hispanic others	< 1%
Nursing Infants (< 1 year old)	< 1%
Non-nursing infants (<1 year old)	< 1%
Females (13+ years, pregnant)	< 1%
Females (13+ years, nursing)	< 1%
Children (1-6 years old)	1%
Children (7-12 years old)	< 1%
Females (20+ years, not pregnant, not nursing)	< 1%

EPA does not consider the chronic dietary risk to exceed the level of concern.

c. *Cancer risk from consumption of PCA and related metabolites*. The Agency has determined that there are three sources of carcinogenic metabolites from the current uses of diflubenzuron and has added these three sources together to estimate the total cancer risk for PCA and related metabolites.

The first source is mushrooms. The Agency used results from mushroom metabolism studies to determine the percent of Total Radioactive Residue (TRR) present as PCA or the related compound CPU in mushrooms. The percent crop treated value for mushrooms, 30%, is an upper bound estimate. The overall U.S. dietary exposure is 0.0000045 mg/kg/day for a risk estimate of 2.9 x 10^{-7}.

For the second source, animal commodities, tolerance levels for diflubenzuron in animal commodities were used and, adjusting for percent crop treated of feed items, total levels of PCA and related compounds were estimated. The overall U.S. dietary exposure is 0.000004 mg/kg/day for a risk estimate of 2.7 x 10^{-7}.

Finally, based on the results of a rat metabolism study, assumption of a 2.0% conversion of diflubenzuron to PCA in humans was assumed. Using the above exposure estimate for rice and currently registered uses of diflubenzuron, the calculated exposure is 0.00008 mg/kg/day for a risk estimate of 1.0 x 10^{-7}.

The total of these three estimates gives a total cancer risk estimate for PCA and related metabolites from all dietary sources of diflubenzuron of 6.6 x 10^{-7}.

2. *From drinking water*. HED has calculated drinking water levels of concern (DWLOCs) for chronic (non-cancer) exposure to diflubenzuron in surface and ground water for the U.S. population and children (1-6 yrs). They are 700 and 200 ppb, respectively. For chronic (cancer) exposure to CPU in surface and ground water, the DWLOC is 0.21 ppb for the U.S. population. To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DRES) 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 acceptable chronic (cancer) exposure to diflubenzuron in drinking water. DWLOCs were then calculated using default body weights and drinking water consumption figures.

a. *Chronic risk*: Chronic RfD = 0.002 mg/kg/day. Maximum H_2O = 0.002 - Food Exposure.

Subgroup	Food Exposure (from DRES mg/kg/day)	Maximum H_2O Exposure (mg/kg/day)
U.S. population	0.000080	0.01992
Children (1-6 years)	0.00021	0.01980

U.S. Population: DWLOC = 700 ppb
Children (1-6 years): DWLOC = 200 ppb

b. Cancer risk: Q* = 6.38 x 10^{-2} (mg/kg/day) -- Maximum H_2O = 1.6 x 10^{-5} - Food Exposure

Subgroup	Food Exposure (mg/kg/day)	Maximum H_2O Exposure (mg/kg/day)
U.S. population	0.0000101	0.0000059

U.S. population: DWLOC = 0.21 ppb

The estimated average concentration of diflubenzuron in surface water sources is not expected to exceed 0.05 ppb. Estimated average concentrations of CPU in surface water sources is not expected to exceed 0.85 ppb. The estimated average concentrations of diflubenzuron in surface water are less than EPA's levels of concern for diflubenzuron in drinking water as a contribution to chronic (non-cancer) aggregate exposure. However, the estimated average concentration (0.85 ppb) of CPU in surface water exceeds EPA's levels of concern for CPU in drinking water (0.21 ppb) as a contribution to chronic (cancer) aggregate exposure.

EPA believes the estimates of CPU exposure in water derived from the PRZM-EXAMS model, particularly the estimates pertaining to chronic exposure, are significantly overstated for several reasons. The PRZM-EXAMS model was designed to estimate exposure from ecological risk assessments and thus uses a scenario of a body of water approximating the size of a 1 hectare (2.5 acres) pond. This tends to overstate chronic drinking water exposure levels for the following reasons. First, surface water source drinking water generally comes from bodies of water that are substantially larger than a 1 hectare (2.5 acres) pond. Second, the modeled scenario also assumes that essentially the whole basin receives an application of the pesticide. Yet in virtually all cases, basins large enough to support a drinking water facility will contain a substantial fraction of the area which does not receive pesticide. Third, there is often at least some flow (in a river) or turnover (in a reservoir or lake) of the water so the persistence of the pesticide near the drinking water facility is usually overestimated. Fourth, even assuming a reservoir is directly adjacent to an agricultural field, the agricultural field may not be used to grow a crop on which the pesticide in question is registered for use. Fifth, the PRZM-EXAMS modeled scenario does not take into account reductions in residue-loading due to applications of less than the maximum application rate or no treatment of the crop at all (percent crop treated data). Although there is a high degree of uncertainty to this analysis, these are the best available estimates of concentrations of CPU in drinking water. EPA believes that these numbers justify asking for field runoff monitoring for CPU in conjunction with the registered use on cotton.

EPA bases this determination on a comparison of estimated concentrations

of diflubenzuron and CPU in surface waters and ground waters to back-calculated ''levels of concern'' for diflubenzuron and CPU in drinking water. These levels of concern in drinking water were determined after EPA has considered all other non-occupational human exposures for which it has reliable data, including all current uses, and uses considered in this action. The estimates of diflubenzuron and CPU in surface and ground waters are derived from water quality models that use conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of concern in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of diflubenzuron and CPU on drinking water as a part of the aggregate risk assessment process.

3. *From non-occupational 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, these uses are expected to result in insignificant risk.

4. *Cumulative exposure to substances with 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.'' An explanation of the current Agency approach to assessment of pesticides with a common mechanism of toxicity may be found in the Final Rule on Bifenthrin Pesticide Tolerances (62 FR 62961).

Diflubenzuron is structurally similar to other substituted benzoylurea insecticides including triflumuron and flucycloxuron. 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.

D. Aggregate Risks and Determination of Safety for U.S. Population, Infants, and Children

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

2. *Chronic*. For the U.S. population, <1% of the RfD is occupied by dietary (food) exposure. The estimated average concentrations of diflubenzuron in surface and ground water are less than OPP's levels of concern for diflubenzuron in drinking water. Therefore, EPA concludes that there is a reasonable certainty that no harm will result to infants, children, or adults from chronic aggregate (food plus water) exposure to diflubenzuron residues.

3. *Carcinogenic aggregate exposure and risk*. For the U.S. population, cancer risk resulting from dietary (food) exposure is 6.6×10^{-7}. The estimated average concentration (0.85 ppb) of CPU in surface water exceeds EPA's levels of concern for CPU in drinking water (0.21 ppb) as a contribution to chronic (cancer) aggregate exposure. However, EPA believes that these PRZM-EXAMS model overestimates exposures for the reasons given above. EPA does not generally use surface water modeling values for quantitative risk assessment. However, due to the statistical uncertainties regarding the significance of cancer risks which are near 1×10^{-6}, EPA has calculated that the cancer risk resulting from 0.85 ppb of CPU in drinking water is 1.55×10^{-6}. The aggregate cancer risk is thus 2.2×10^{-6} (6.6×10^{-7} for food + 1.55×10^{-6} for water).

4. *Determination of safety*. EPA believes that the total risk estimate for CPU in food and drinking water of 2.2×10^{-6} generally represents a negligible risk, as EPA has traditionally applied that concept. EPA has commonly referred to a negligible risk as one that is at or below 1 in 1 million (1×10^{-6}). Quantitative cancer risk assessment is not a precise science. There are a significant number of uncertainties in both the toxicology used to derive the cancer potency of a substance and in the data used to measure and calculate exposure. The Agency does not attach great significance to numerical estimates for carcinogenic risk that differ by approximately a factor of 2.

III. Other Considerations

A. Metabolism in Plants and Animals

The qualitative nature of the residue in plants is adequately understood based on data from citrus, mushroom, and soybean metabolism studies. The Agency has concluded that tolerances should be expressed in terms of the combined residues of diflubenzuron and metabolites convertible to PCA (CPU and PCAA) expressed as diflubenzuron. However, for the purposes of this temporary tolerance petition, diflubenzuron *per se* should be the regulated residue in plants.

The nature of the residue in animals is adequately understood based on acceptable poultry and ruminant metabolism studies reflecting oral dosing. Terminal residues identified in animal tissues, milk, and eggs include diflubenzuron, 2-hydroxy-diflubenzuron (2HDFB), 2,6-difluorobenzamide (DFBAM), 2,6-difluorobenzoic acid (DFBA), N-(4-chlorophenyl)urea (CPU), and PCA. For the purposes of this temporary tolerance petition, diflubenzuron should be the regulated residue in animals.

B. Analytical Enforcement Methodology

Adequate methods are available for the analysis of Diflubenzuron in rice grain (0.01 ppm), rice straw (0.01 ppm) and water (0.001 ppm). The method for measuring PCA in rice grain recovers only about 50% at the 0.025 ppm level. As part of the reregistration of diflubenzuron, the Agency concluded that tolerances should be expressed in terms of the combined residues of diflubenzuron and metabolites. Until suitable methodology is developed, regulation of diflubenzuron *per se* is an acceptable alternative. 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. The FDA PESTDATA data base dated 1/94 (PAM Vol. I, Appendix II) contains no information on diflubenzuron recovery using Multiresidue Methods PAM, Vol. I Sections 302, 303, and 304. However, the registrant has submitted multi-residue testing data that the Agency has forwarded to the FDA.

C. Magnitude of Residues

Uniroyal Chemical Company submitted data from 10 tests depicting residues of diflubenzuron in/on rice.

Ten trials were conducted in Arizona (2), California (2), Louisiana (1), Mississippi (2), and Texas (3). At each site rice grain and straw were harvested at normal maturity following one broadcast application of diflubenzuron (25% WP, EPA Reg. No. 400-465; 2 lb/gal FlC, EPA Reg. No. 400-461) at 0.25 lb. ai/A (1x the maximum proposed application rate). A single application was made 10 days or 2 weeks following permanent flood or rice emergence, respectively. Applications of the WP/D and FlC formulation were made in 10 gal of water/A using ground equipment. Aerial applications of the FlC formulation were made at 5-10 gal of water/A. Residues of diflubenzuron and PCA in/on treated rice grain were <LOQ for all samples. The submitted field trial data indicate that residues of diflubenzuron will not exceed the proposed temporary tolerance of 0.01 ppm in/on rice grain. As an adjunct to the magnitude of the residue study on rice, the petitioner also conducted residue studies to determine the magnitude of the residue of diflubenzuron in treated rice flood waters. Residue levels were determined from samples taken from the treated and untreated plots of the diflubenzuron crop field trials. Five trials were conducted in California (2), Louisiana (1), and Texas (2). Following one broadcast application of diflubenzuron as a 25% WP formulation or 2 lb/gal FlC formulation at 0.25 lb. ai/A (1x the maximum proposed application rate) as described in the crop field trial discussion, one control and duplicate treated samples of water were collected from each plot at each test site at intervals of 0, 1, 3, 7, 14, 21, and 28 days following insecticide application. For the sampling intervals 0, 1, 3 and 7 days after application of diflubenzuron at 1x the maximum proposed application rate (0.25 lb. ai/A), residues of diflubenzuron in treated rice flood waters were 0.011 to 0.04 ppm, 0.0007 to 0.027 ppm, <0.0003 to 0.020 ppm, and <0.0003 to 0.0014 ppm; residues were <LOQ for all samples collected 14 or more days after treatment.

There are several active SLNs [SLN Nos. AL930004, FL910004, HI940003, CA850041, CA870049, and NV940003] which allow the application of diflubenzuron to water at a maximum rate 0.25 lb. ai/A for mosquito abatement. Labels prohibit the use of treated water for irrigation or human consumption. The proposed label recommends the retention of flood waters for 14 days to allow for the dissipation of diflubenzuron residues. Residue data indicate that diflubenzuron residues >LOQ may be present in rice flood waters <14 days after application of diflubenzuron.

D. Magnitude of the Residue in Processed Commodities

Uniroyal Chemical Company submitted data depicting the potential for concentration of diflubenzuron residues in the processed commodities of rice. Two tests were conducted in Mississippi (1) and Texas (1). At each site, rice grain was harvested at maturity, 82 to 85 days following a post-permanent flood application of the 2 lb/gal FlC formulation at 2 lb. ai/A (8x the proposed maximum application rate). Samples were processed according to simulated commercial procedures into hulls, bran, and polished rice. Residues of diflubenzuron were non-detectable (LOQ <0.01 ppm) and 0.26 and 0.87 ppm in four treated samples of the RAC, and did not concentrate in processed commodities of rice harvested 82 to 85 days following a single 2 lb. ai/A (8x) of diflubenzuron. As the residues of diflubenzuron did not concentrate in the hull, bran, or whole rice fractions of processed rice grain, a tolerance for residues in rice processed commodities is not required.

E. Magnitude of Secondary Residues in Meat/Milk/Poultry/Eggs

Rice grain, straw, hulls and bran may be fed to livestock and/or poultry. However, the incremental exposure of diflubenzuron residues to livestock and poultry is minimal when compared to the existing exposure. EPA concludes that the current tolerances on meat, milk, poultry and eggs are adequate to cover the added residues resulting from the experimental use on rice.

F. International Residue Limits

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

G. Rotational Crop Restrictions.

The nature of the residue in rotational crops is adequately understood for purposes of reregistration (residue chemistry chapters for the Reregistration Eligibility Decision (RED) document, March 16, 1995). Although EPA concluded that the available confined rotational crop study was inadequate to fully satisfy GLN 165-1 reregistration requirements, another confined rotational crop study will not be required because the study allowed EPA to make regulatory conclusions regarding the need for limited rotational crop studies (GLN 165-2) and to comment on the appropriateness of the currently established plantback interval (PBI) on diflubenzuron end-use product labels.

Residue data on field-grown rotational crops are not available. Although the confined study was deemed inadequate, the available data indicate that diflubenzuron and CPU may exceed 0.01 ppm in rotational crops planted up to 4 months after a 1x application of diflubenzuron to the primary crop and in cereal grains planted up to 12 months after a 1x application.

IV. Conclusion

Therefore, the temporary tolerance is established for residues of the insecticide diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and metabolites convertible to p-chloroaniline expressed as diflubenzuron on rice grain at 0.01 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 13, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the

material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300660] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

This final rule establishes a temporary tolerance for the residues of diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and metabolites convertible to p-chloroaniline expressed as diflubenzuron on rice grain at 0.01 ppm 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) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or 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 in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances for the residues of diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and metabolites convertible to p-chloroaniline expressed as diflubenzuron on rice grain at 0.01 ppm 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. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

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 the rule in the **Federal Register**. This 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: May 7, 1998.

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. 346a and 371.

2. By revising § 180.377 to read as follows:

§ 180.377 Diflubenzuron; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide diflubenzuron (*N*-[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide) in or on the following raw agricultural commodities:

Commodity	Parts per million
Artichokes	6.0
Cattle, fat	0.05
Cattle, mbyp	0.05
Cattle, meat	0.05
Cottonseed	0.2
Eggs	0.05
Goats, fat	0.05
Goats, mbyp	0.05
Goats, meat	0.05
Grapefruit	0.5
Hogs, fat	0.05
Hogs, mbyp	0.05
Hogs, meat	0.05
Horses, fat	0.05

Commodity	Parts per million
Horses, mbyp	0.05
Horses, meat	0.05
Milk	0.05
Mushrooms	0.2
Orange	0.5
Poultry, fat	0.05
Poultry, mbyp	0.05
Poultry, meat	0.05
Sheep, fat	0.05
Sheep, mbyp	0.05
Sheep, meat	0.05
Soybeans	0.05
Tangerine	0.5
Walnuts	0.1

(2) A temporary tolerance expiring June 30, 1999, is established for residues of the insecticide diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and metabolites convertible to p-chloroaniline expressed as diflubenzuron on rice grain at 0.01 ppm.

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

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for residues of diflubenzuron in or on the following raw agricultural commodities:

Commodity	Parts per million
Grass, pasture	1.0
Grass, range	3.0

(d) Indirect or inadvertent residues. [Reserved]

[FR Doc. 98–12640 Filed 5–12–98; 8:45 am]

BILLING CODE 6560–50–F

GENERAL SERVICES ADMINISTRATION

41 CFR Chapter 301

[FTR Amendment 72]

RIN 3090–AG72

Federal Travel Regulation; Maximum Per Diem Rates

AGENCY: Office of Governmentwide Policy, GSA.

ACTION: Final rule.

SUMMARY: This final rule amends the Federal Travel Regulation (FTR) to change the maximum per diem rate prescribed in FTR Amendment 68 (62 FR 63798, December 2, 1997) for El Paso (El Paso County), Texas.

The General Services Administration (GSA), after an analysis of additional data, has determined that the current lodging allowance for El Paso, Texas does not adequately reflect the costs of lodging accommodations near Federal Government facilities. To provide adequate per diem reimbursement for Federal employee travel to El Paso, Texas, the maximum lodging allowance is being changed to $78 and the meals and incidental expenses (M&IE) rate remains at $34, resulting in a maximum per diem rate of $112.

EFFECTIVE DATE: This final rule is effective May 13, 1998, and applies for travel performed on or after May 13, 1998.

FOR FURTHER INFORMATION CONTACT: Joddy Garner, General Services Administration, Travel and Transportation Management Policy Division (MTT), Washington, DC 20405, telephone 202–501–1538.

SUPPLEMENTARY INFORMATION: GSA has determined that this rule is not a significant regulatory action for the purposes of Executive Order 12866 of September 30, 1993. This final rule is not required to be published in the **Federal Register** for notice and comment. Therefore, the Regulatory Flexibility Act does not apply. This rule is also exempt from Congressional review prescribed under 5 U.S.C. 801 since it relates solely to agency management and personnel.

For the reasons set out in the preamble, under 5 U.S.C. 5701-5709 title 41, Chapter 301 of the Code of Federal Regulations is revised to read as follows:

CHAPTER 301—TRAVEL ALLOWANCES

Appendix A to chapter 301 is amended by removing the corresponding lodging, M&IE, and maximum per diem rates for El Paso, Texas, and inserting in their places the following entry:

Appendix A To Chapter 301—Prescribed Maximum Per Diem Rates For Conus

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El Paso El Paso 78 34 112

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Dated: May 6, 1998.

David J. Barram,

Administrator of General Services.

[FR Doc. 98–12827 Filed 5–12–98; 8:45 am]

BILLING CODE 6820–14–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

45 CFR Parts 1215 and 2507

RIN 3045–AA16

Freedom of Information Act Regulation and Implementation of Electronic Freedom of Information Act Amendments of 1996

AGENCY: Corporation for National and Community Service.

ACTION: Final rule.

SUMMARY: The Corporation for National and Community Service (hereinafter the ''Corporation'') has revised its regulations under the Freedom of Information Act (FOIA). The Corporation redesignated the existing regulations under former ACTION's CFR chapter as updated regulations under the Corporation's CFR chapter. These procedures facilitate the public's access to Corporation records, and implement the Electronic Freedom of Information Act Amendments of 1996.

DATES: This final rule is effective June 12, 1998.

FOR FURTHER INFORMATION CONTACT: Bill Hudson, Corporation FOIA/Privacy Act Officer, at (202) 606–5000, ext. 265.

SUPPLEMENTARY INFORMATION: The Corporation published a notice of proposed rulemaking on March 12, 1998 (63 FR 12068) announcing its intention to redesignate the existing regulations under former ACTION's CFR chapter as updated regulations under the Corporation's CFR chapter. The functions of the ACTION agency, including the VISTA and senior volunteer programs, were transferred to the Corporation on April 4, 1994. The Corporation operates under two statutes, the National and Community Service Act of 1990, as amended, 42 U.S.C. 12501 *et seq.*, and the Domestic Volunteer Service Act of 1973, as amended, 42 U.S.C. 4950 *et seq.*

The Corporation received only two comments on this proposed rule. One comment requested that the Corporation publish a more detailed index list of documents available on its internet web site. The Corporation's FOIA Officer will publish a more detailed index list on its internet web site as additional types of documents become available on that site. The other comment was a request to grant the Corporation's Office of Inspector General (OIG) authority to make the final determination on all FOIA appeals where the OIG denied the initial request for any document in its possession. The Corporation has determined that its Chief Operating