Dated: April 8, 1999.

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 180.446 is amended as follows:

a. By adding a paragraph heading to paragraph (a).

b. By redesignating paragraphs (b) and (c) as paragraphs (a)(1) and (a)(2), respectively.

c. By amending newly designated paragraph (a)(1) by adding alphabetically to the table the commodity ''apple pomace'' and revising the tolerance for ''apples''.

d. By adding and reserving with paragraph headings new paragraphs (b), (c) and (d).

The added and revised portions read as follows:

§ 180.446 Clofentezine; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* * *	* *
Apple pomace	3.0
Apples	0.5
* * *	* *

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

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

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

[FR Doc. 99–9710 Filed 4–16–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300844; FRL–6075–4]

RIN 2070–AB78

Diflubenzuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and its metabolites, 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA) in/on rice grain at 0.02 ppm and rice straw at 0.8 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 these tolerances.

DATES: This regulation is effective April 19, 1999. Objections and requests for hearings must be received by EPA on or before June 18, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300844], 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–300844], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), 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. 119, 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–300844]. 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: Rita Kumar, 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) 308–8291, e-mail: kumar.rita@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 Experimental Use Permit, and 8F4925, to amend 40 CFR 180.377 to include a permanent 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. Background and Statutory Findings

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 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 its metabolites, 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA) on rice grain at 0.02 parts per million (ppm) and rice straw at 0.8 ppm, 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 its metabolites, 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA) on rice grain at 0.02 ppm and rice straw at 0.8 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 (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and its metabolites, 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA) on rice grain at 0.02 ppm and rice straw at 0.8 ppm 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.

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. Since an oral NOAEL was selected for a dermal endpoint, a dermal absorption factor of 0.5% should be 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*. 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 1 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.

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 NOEL 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 [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. Based on the developmental and reproductive toxicity studies discussed above, for diflubenzuron there does not appear to be an extra sensitivity for pre- or post-natal 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.

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 were calculated in livestock, citrus and mushroom commodities. Anticipated residue estimates for diflubenzuron were not calculated for other 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.

Dietary exposure estimates were based on the following percent crop treated estimates: grass/rangeland, 1%; cottonseed, 3%; grapefruit, 8%; mushrooms, 3.1%; oranges, 2%; tangerines, 4%; soybean, 1%; cattle bolus, 5%. Other commodities were assumed to be 100% treated. The Agency believes that the three conditions listed above have been met. With respect to (1), EPA finds that the percent crop treated 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.

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 chronic DEEM analysis used mean consumption (3–day average). Anticipated residues and percent crop treated information for select commodities were used. Since EPA determined to reduce the 10x factor to 1x, the Population Adjusted Dose (PAD) and the RfD are the same. Therefore, EPA's level of concern are values >100% RfD. Dietary exposures for the U.S. general population and other subgroups at percentage of RfD are presented below. The other subgroups included represent the highest dietary

exposures for their respective subgroups (i.e., children, females, and the other general population subgroup higher than U.S. population).

Subgroups	%RfD	Exposure (mg/kg/day)
U.S. population (48 states)	<1%	0.000027
Non-hispanic others	<1%	0.000102
Non-nursing infants (<1 year old)	<1%	0.000031
Females (20+ years, not pregnant, not nursing)	<1%	0.000032

The U.S. population and all the DEEM subgroups have ARCs for chronic dietary (non-cancer) risk from diflubenzuron well below the RfD when all uses are considered.

c. *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): residues in plants/fungi (mushrooms), residues in animal commodities (milk and liver) and *in vivo* conversion of diflubenzuron.

i. *Mushrooms/milk/liver*. The Agency used results from metabolism studies to determine the percent of the total radioactive residue (TRR) present as PCA and related compounds in mushrooms, milk and liver. For milk and liver, anticipated residues were calculated from the results of the ruminant feeding study using tolerance level residues in animal feed items and adjusting for percent crop treated. The total levels of PCA and related compounds were estimated by multiplying the ratio of PCA/DFB by the diflubenzuron consumption (from DEEM). The PCA consumption values were calculated as follows:

Mushrooms = 0.0000062 mg/kg/day
Milk = 0.0000004 mg/kg/day
Liver = 0.00000002 mg/kg/day
Total = 0.00000066 mg/kg/day
Overall U.S.: 0.0000066 mg/kg/day (4.2 x 10^{-7} Carcinogenic Risk)

ii.*In vivo*. Based on the results of a rat metabolism study, an assumption of a 2.0% conversion of diflubenzuron to PCA in humans is assumed for PCA risk assessment. Using the above exposure estimate for rice and published uses (0.000027 mg/kg/day) the carcinogenic risk estimate (overall U.S. population) is 3.4 x 10^{-8} (0.000027 mg/kg/day x 0.02 x 0.0638 $(mg/kg/day)^{-1}$).

Total cancer risk estimate for PCA and related metabolites:

Overall U.S.: 4.5 x 10^{-7}

This cancer risk does not exceed the level of concern.

2. *From drinking water*. EPA 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 0.30 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 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 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 = 0.02 mg/kg/day. Maximum H_2O = 0.02 - Food Exposure.

Subgroup	Food Exposure to Diflubenzuron (from DEEM mg/kg/day)	Maximum H_2O Exposure (mg/kg/day)
U.S. population	0.000027	0.01997
Children (1-6 years)	0.00031	0.01997

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 to PCA and Related Compounds (mg/kg/day)	Maximum H_2O Exposure (mg/kg/day)
U.S. population	0.0000071	0.0000089

U.S. population: DWLOC = 0.30 ppb

The PCA and related compounds value is a total of residues in food (0.0000066 mg/kg/day) + residues formed *in vivo* (0.000027 mg/kg/day DFB x 2% conversion).

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 0.73 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 (0.73 ppb) of CPU in surface water exceeds EPA's levels of concern for CPU in drinking water (0.30 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 risks.

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 food exposure. The estimated average concentrations of diflubenzuron in surface and ground water are less than EPA'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 food exposure is 4.5×10^{-7}. The estimated average concentration (0.73 ppb) of CPU in surface water exceeds EPA's levels of concern for CPU in drinking water (0.30 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 0.73 ppb of CPU in drinking water is 1.30×10^{-6}. The aggregate cancer risk is thus 1.8×10^{-6} (4.5×10^{-7} for food + 1.3×10^{-6} for water).

4. *Determination of safety*. EPA believes that the total risk estimate for CPU in food and drinking water of 1.8×10^{-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.

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. 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.

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). 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. Individual analytical methods for rice commodities have been submitted for CPU (LOQ of 0.001 ppm in grain, 0.01 ppm in straw) and PCA (LOQ of 0.005 ppm in grain and straw). The methods and ILVs have been sent to Beltsville for Petition Method Validation. EPA will withhold a final conclusion on the adequacy of these method as analytical enforcement methods pending receipt of the PMV reports. However, these methods are based on Method II. EPA thus has no objections to a conditional registration while the PMV of the methods for PCA and CPU in rice commodities is performed.

C. Multiresidue Methods

The FDA PESTDATA data base dated January 1, 1994 (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 Multiresidue testing data that the Agency has forwarded to the Food and Drug Administration (FDA). Also, the results of Multiresidue Method testing of PCA and CPU have been submitted and will be forwarded to FDA.

D. Storage Stability Data

Data from a 12–month storage stability study were submitted depicting the magnitude of residue of diflubenzuron (DFB) and its metabolites CPU and PCA in/on rice grain, straw, bran and hulls (MRID # 44699202). Diflubenzuron was determined to be stable over a 12–month period with average recoveries of 78% (grain), 99% (bran), 89% (straw), and 78% (hulls). CPU exhibited the following average recoveries of a 12–month period: 76% (grain), 99% (bran), 89% (straw), and 78% (hulls). Significant declines in the PCA concentration were observed, decreasing rapidly to 56% (average) after 1 month and to 30% (average) after 12 months. The storage stability of diflubenzuron and CPU in/on rice commodities have been adequately demonstrated. PCA is unstable, degrading significantly after 1 month. Therefore, for magnitude of residue samples with storage periods greater than 1 month, correction factors must be used in order to determine the residue levels that were present at the time of sample collection.

E. Magnitude of Residues

A total of 14 acceptable field trials have been conducted: Region IV (9 trials), Region VI (2 trials), and Region X (3 trials). EPA requires that a minimum of 16 field trials be performed. The Agency suggests the following distribution for the field trials: Region IV (11 trials), Region V (1 trial), Region VI (2 trials), and Region X (2 trials) (Residue Chemistry Test Guidelines, OPPTS 860.1500 Crop Field Trials Tables 1 and 6). Additional field trials are thus required in Regions IV (1 trial) and V (1 trial). EPA has decided to issue a conditional registration for the use of diflubenzuron on rice until the necessary field trials are performed.

Residues of diflubenzuron, CPU and PCA in/on treated rice grain were <0.01 ppm, <0.001 - 0.002 ppm and <0.005 ppm, respectively, and the combined residues were <0.016 - <0.017 ppm. Residues of diflubenzuron, CPU and PCA in treated straw samples were <0.01 - 0.57 ppm, <0.01 - 0.02 ppm and <0.005 - 0.021 ppm, respectively, and the combined residues were <0.025 - <0.607 ppm. The residue data support the proposed tolerance of 0.02 ppm for diflubenzuron in/on rice grain and 0.8 ppm in/on rice straw.

F. 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, 82-85 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. 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.

G. 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 use on rice.

H. Magnitude of Residues in Water, Fish, and Irrigated Crops

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), 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 - 0.04 ppm, 0.0007-

0.027 ppm, <0.0003 - 0.020 ppm, and <0.0003 - 0.0014 ppm; residues were <LOQ for all samples collected 14 or more days after treatment.

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.

I. 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 tolerance.

J. 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 on diflubenzuron end-use product labels.

Uniroyal has submitted data depicting diflubenzuron residues in representative rotational crops from two limited field trials. Provided the petitioner explains the discrepancy in the 0.10 ppm residue value reported for diflubenzuron in one of the wheat forage samples from CA, the limited field rotational crop study is adequate. The available data indicate that tolerances for diflubenzuron residues in rotational crops will not be required provided the diflubenzuron labels specify a restriction for the planting of rotation crops of at least 30 days.

IV. Conclusion

Therefore, tolerances are established for residues of the insecticide diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and its metabolites, 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA) on rice grain at 0.02 ppm and rice straw at 0.8 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 June 18, 1999, 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 under the ''ADDRESSES'' section (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–300844] (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. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), 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 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 0.02 ppm and rice straw at 0.8 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 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 0.02 ppm and rice straw at 0.8 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.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and 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: April 7, 1999.

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. In § 180.377, by revising paragraph (a)(2) to read as follows:

§ 180.377 Diflubenzuron; tolerances for residues.

(a) * * *

(2) Tolerances are established for residues of the insecticide diflubenzuron (N-[[4-chlorophenyl)amino]-carbonyl]-2,6-difluorobenzamide) and its metabolites 4-chlorophenylurea and 4-chloroaniline on rice grain at 0.02 ppm and rice straw at 0.8 ppm.

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[FR Doc. 99–9711 Filed 4–16–99; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 43 and 63

[IB Docket No. 98–118, FCC 99–51]

Biennial Review of International Common Carrier Regulations

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: On March 18, 1999, the Federal Communications Commission adopted a Report and Order (Order) to further streamline the rules governing international common carriers. The new rules will benefit U.S. consumers because they will eliminate unnecessary regulatory delay and will facilitate entrance into the international telecommunications market. The Commission believes that the new rules will lessen the regulatory burdens on applicants, authorized carriers, and the