Dated: April 29, 1998

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is corrected as follows:

PART 180—[CORRECTED]

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

Authority: 21 U.S.C. 346a and 371.

2. By correcting § 180.527, to read as follows:

§ 180.527 N-(4-fluorophenyl)-N-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide; tolerances for residues.

(a) *General.* (1) Time-limited tolerances are established for combined residues of the herbicide, *N*-(4-fluorophenyl)-*N*-(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide and its metabolites containing the 4-fluoro-*N*-methylethyl benzenamine moiety in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/Revocation Date
Corn, field, forage ..	0.4	4/30/03
Corn, field, grain	0.05	4/30/03
Corn, field, stover ...	0.4	4/30/03
Soybean seed	0.1	4/30/03

(2) Residues in these commodities not in excess of the established tolerance resulting from the use described in paragraph (a) of this section remaining after expiration of the time-limited tolerance will not be considered to be actionable if the herbicide is applied during the term of and in accordance with the provisions of the above regulation.

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

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

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

[FR Doc. 98–12490 Filed 5–12–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300661; FRL–5790–8]

RIN 2070–AB78

Bromoxynil; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for bromoxynil and DBHA in or on cotton. In addition, this regulation establishes tolerances for bromoxynil and DBHA in or on meat, meat by products, and fat of cattle, hogs, horses, goats, and sheep. Further, this regulation establishes tolerances for bromoxynil and DBHA in milk, eggs, and poultry meat, meat by-products, and fat. Rhone-Poulenc Ag Company requested the tolerances for cotton under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170).

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–300661], 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–300661], 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 5.1/6.1 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–300661]. 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: Jim Tompkins, 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, 703-305-5697, e-mail: tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 26, 1997 (62 FR 63170) (FRL–5755–6), 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) 3F4233 for tolerance by Rhone-Poulenc Ag Company. This notice included a summary of the petition prepared by Rhone-Poulenc Ag Company, the registrant. Comments in response to the notice of filing were received from public interest groups, individual concerned citizens, agricultural extension agents, representatives of State agencies, individual growers, and industry groups. The issues raised were the same issues raised in response to the proposed rule (May 2, 1997, 62 FR 24065) (FRL–5617–5) for the bromoxynil tolerance that expired on January 1, 1998. Many of the comments are addressed in this document. Responses to other significant comments are presented in Unit III. of the final rule for last year's tolerance (June 18, 1997, 62 FR 33019) (FRL–5724–9) or in a Response to Comments document that has been included in the docket for that action.

The petition requested that 40 CFR 180.324 be amended by establishing tolerances for residues of the herbicide bromoxynil plus its metabolite DBHA (3,5-dibromo-4-hydroxybenzoic acid) resulting from the application of octanoic and heptanoic acid esters of bromoxynil to cotton: undelinted cottonseed at 7 parts per million (ppm), cotton gin byproducts at 50 ppm, and cotton hulls at 21 ppm. (Active ingredient codes are 35302 for the octanoic acid ester, and 128920 for the heptanoic acid ester. CAS Reg. Nos. are

1689-99-2 for the octanoic acid ester, and 56634-95-8 for the heptanoic acid ester.) The tolerances established in this final rule differ from these tolerances proposed by the registrant as the result of the review of residue data for bromoxynil and DBHA in cotton commodities submitted by the registrant after the petition was filed. In addition, the petition requested that the maximum allowable cotton acreage that can be treated annually with bromoxynil be increased from 400,000 acres to 1.3 million acres.

In the **Federal Register** of May 24, 1995 (60 FR 27414) (FRL–4953–9), EPA established a time-limited tolerance under section 408 of the FFDCA, 21 U.S.C. 346a, for residues of the herbicide bromoxynil, (3,5-dibromo-4-hydroxybenzonitrile) on cottonseed. This tolerance expired on April 1, 1997. The tolerance was established in response to a petition filed by the Rhone-Poulenc AG Company, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709.

In the **Federal Register** of May 2, 1997 (62 FR 24065), EPA issued a proposed rule for establishment of tolerances on cotton commodities and poultry, eggs, and milk, and revision of tolerances on other livestock. In the **Federal Register** of June 18, 1997 (62 FR 33019), EPA issued a final rule for establishment of tolerances on cotton commodities and poultry, eggs, and milk, and revision of tolerances on other livestock. The tolerances for the cotton commodities expired on January 1, 1998.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to the pesticide residues from treated food and contaminated drinking water is typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of the Food Quality Protection Act of 1996 (FQPA), this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure

can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

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 bromoxynil and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for bromoxynil and DBHA on undelinted cottonseed at 1.5 ppm; cotton gin byproducts at 7.0 ppm; and cotton hulls at 5.0 ppm; in or on cattle, hogs, horses, goats, and sheep at 0.5 ppm in meat, 3.5 ppm in meat by-products (mbyp), and 1.0 ppm in fat; at 0.1 ppm in milk; at 0.05 ppm in eggs; at 0.05 ppm in poultry meat and fat; and at 0.3 ppm in poultry mbyp. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances 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 bromoxynil are discussed in the proposed rule (May 2, 1997, 62 FR 24065).

B. Toxicological Endpoints

The toxicological endpoints for bromoxynil are discussed in Unit IV. ''Dose Response Assessment'' of the proposed rule for last year's tolerance (May 2, 1997, 62 FR 24065).

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.324) for the residues of bromoxynil, in or on a variety of raw agricultural commodities. Tolerances for the residues of bromoxynil, resulting from the application of octanoic and heptanoic acid esters of bromoxynil to cotton, have been established in or on cattle, hogs, horses, goats, and sheep at 0.5 ppm in meat, 3.0 ppm in mbyp, and 1.0 ppm in fat. Tolerances for residues of bromoxynil, resulting from the application of octanoic and heptanoic acid esters of bromoxynil to cotton have been established at 0.1 ppm in milk; and at 0.05 ppm in eggs; at 0.05 ppm in poultry meat, mbyp, and fat. Risk assessments were conducted by EPA to assess dietary exposures and risks from bromoxynil as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. A revised acute dietary risk assessment was conducted for bromoxynil. This revised acute dietary assessment differs from the assessment used for last year's tolerance as follows: (a) The results of a new cotton residue study were used to determine anticipated bromoxynil residues; (b) a probabilistic assessment submitted by the registrant was used. The acute assessment used a NOEL of 4 milligram/kilograms body weight/day (mg/kg bw/day) based on developmental effects with the population subgroup of concern being females ≥13 years old and a NOEL of 8 mg/kg bw/day based on systemic effects for all populations except females ≥13 years old. The acute analysis estimates the distribution of single-day exposures for the overall U.S. population and certain subgroups. The MOE is a measure of how closely the exposure comes to the NOEL and is calculated as a ratio of the NOEL to the exposure. The calculated MOE for acute risk of bromoxynil for the general U. S. Population is >58,000 and for females ≥13 years old is >24,000. For the most exposed subgroups, the calculated MOE for acute risk of bromoxynil is >32,000 for non-nursing infants, >36,000 for all infants, and >35,000 for children 1-6 years old. These figures are above the required MOE of 1,000 for females ≥13 years old and 100 for the general population and all other population subgroups, indicating that the potential for an adverse effect from a single day exposure is unlikely. The level of concern for the general U.S. population and all population subgroups except for females ≥13 years is based on interspecies extrapolation (10x) and intraspecies variability (10x). For females ≥13 years, an added factor of 10x is used pursuant to section 408(b)(2)(C) (See Unit II.E.b. of this document).

ii. *Chronic exposure and risk.* For chronic exposure to bromoxynil, the reference dose (0.015 mg/kg/day) is based upon a NOEL/LOEL of 1.5 mg/kg/day, from a 1-year canine study, with additional uncertainty factors applied

for intra- (10x) and interspecies (10x) variability.

A DRES chronic exposure analysis was conducted using anticipated residue levels for all registered commodities and livestock, and percent crop treated information to estimate dietary exposure for the general population and several population subgroups. The chronic analysis showed that for chronic effects other than cancer, for all population subgroups, less than 1% of the reference dose was consumed.

When EPA establishes, modifies, or leaves in effect a tolerance, section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided five years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than five years from the date of issuance of this tolerance.

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

The Agency used percent crop treated (PCT) information as follows. A routine chronic dietary exposure analysis for bromoxynil was based on 10% of the cotton crop treated, 10% of all cereal grain crops (wheat, corn, oats, barley, rye, sorghum) treated, 62% of the onion crop treated, 100% of the garlic crop treated, and 71% of peppermint and spearmint crop treated. PCT of 10% for cotton was based on the petitioner's request that the Agency permit up to 1.3 million acres of cotton to be treated annually with bromoxynil, which amounts to 10% of the cotton crop grown in the U.S. The registration of bromoxynil will restrict treatment of bromoxynil on cotton to no more than 1.3 million acres during 1998.

The Agency believes that the three conditions listed above have been met. With respect to (a), EPA finds that the PCT information described above for bromoxynil used on cotton is reliable and has a valid basis. The registration of bromoxynil will restrict treatment of bromoxynil on cotton to no more than 1.3 million acres during 1998. Before the petitioner can increase the treatment of greater than 1.3 million acres of cotton per year, permission from the Agency must be obtained. For crops other than cotton, the Agency has utilized the latest statistical data from RFF (Resources For The Future), Doane, and the U.S. Department of Agriculture (USDA), the best available sources for such information. As to (b) and (c), regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the consumption of food bearing bromoxynil in a particular area.

The cancer risk from all food sources is 1.5 in a million if 10% of the cotton is treated. These risk estimates are based on anticipated residues and percent crop treated information.

2. *From drinking water.* Based on the chemical characteristics and monitoring data, bromoxynil residues are not expected to be found in ground water. For the action last year (June 18, 1997, 62 FR 33019), an analysis of surface water based on cotton use was conducted using the PRZM-EXAMS computer model (Pesticide Root Zone Model Version 2.3 plus Exposure Analysis Modeling System Version 2.94). The maximum or peak estimated concentration for bromoxynil was 12.3 parts per billion (ppb) and the maximum estimated long-term mean was 0.24 ppb (based on modeling using 36 years of weather data). These values represent what might be expected in a small water body near a cotton field highly prone to runoff. The maximum peak estimated concentration for bromoxynil from the model correlates with the highest value detected in the U.S. Geological Survey (USGS) monitoring data, 12.2 ppb, which has been corrected for an analytical recovery rate of 50%. For this action, the Agency has reevaluated the concentrations of bromoxynil in surface water to be used to assess risk associated with drinking water. EPA reviewed USGS national monitoring data and determined which of these sites were likely to have bromoxynil use. To estimate a reasonable high end exposure, EPA focussed on the calculated time weighted annual mean concentrations of bromoxynil at each of 11 USGS monitoring sites, which the EPA views as located in watersheds likely to have bromoxynil use. (These values were not corrected for the analytical recovery rate of 50%.) These time weighted annual mean concentrations ranged from 0.011 ppb to 0.18 ppb, with 10 out of the 11 sites with time weighted annual mean concentrations below 0.05 ppb. Six of the 10 sites had time weighted annual mean concentrations at or below 0.014 ppb. The highest annual time-weighted mean (0.18 ppb) was located in a relatively small watershed (approximately 100 square miles) and a relatively small water body, and the calculated annual mean value at this site was significantly influenced by the presence of a single high value (the highest value found in all of the available monitoring data). Based on this information, EPA believes that 0.05 ppb is a reasonable high end estimate for purposes of estimating drinking water exposure. However, EPA is imposing surface water monitoring requirements as a condition of registration to allow use of more precise estimates in the future.

i. *Acute exposure and risk.* Acute drinking water exposure was calculated by multiplying the estimated concentration of bromoxynil in surface water (12.3 ppb) by the estimated water consumption (2 liters for adults, 1 liter for children) and then dividing by body weight (70 kg for males, 60 kg for females, and 10 kg for children). Acute drinking water exposure is calculated to be 3.5×10^{-4} mg/kg/day for adult males and females, and 1.2×10^{-4} mg/kg/day for children. The MOE for drinking water for all three population subgroups is >10,000.

ii. *Chronic exposure and risk.* Chronic drinking water risk was calculated in the same way as acute risk, except that

the estimated mean concentrations of 0.24 ppb, 0.05 ppb, and 0.01 ppb were used. At 0.24 ppb, the highest of these concentrations, chronic drinking water exposure is calculated to be 2 x 10^{-5} mg/kg/day for children, 7 x 10^{-6} mg/kg/day for males, and 8 x 10^{-6} mg/kg/day for females. All of these exposures are <1% of the RfD of 0.015 mg/kg/day. The cancer risk (calculated based on a 70-year lifetime) is calculated to be 8 x 10^{-7} at a chronic water exposure concentration of 0.24 ppb, 2 x 10^{-7} at a concentration of 0.05 ppb, and 3 x 10^{-8} at a concentration of 0.01 ppb. The Agency has determined that a concentration of 0.05 ppb for bromoxynil is a reasonable high end of exposure for bromoxynil in surface water; therefore, the cancer risk from exposure to bromoxynil in drinking water is calculated at 2 x 10^{-7}.

EPA believes the estimates of bromoxynil 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 for 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 the pesticide. Third, there is often at least some flow (in a river) or turn over (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).

3. *From non-dietary exposure.* Bromoxynil is currently not registered for use on any residential non-food sites.

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.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether bromoxynil 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, bromoxynil 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 bromoxynil has a common mechanism of toxicity with other substances.

C. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* The MOE for all dietary sources (food plus water) is >16,000 for the entire U.S. population, >11,000 for females ≥13 years old, and >5,000 for children 1-6 years old. These MOEs are greater than the levels of concern of 1,000 for females ≥13 years and 100 for all other population groups. Accordingly, EPA concludes that there is a reasonable certainty that no harm will result to the general population and major identifiable population subgroups from aggregate acute exposure to bromoxynil.

2. *Chronic risk.* Using the exposure assumptions described above, EPA has concluded that aggregate exposure to bromoxynil from food and drinking water will utilize <1% of the RfD for the U.S. population. EPA has also concluded that aggregate exposure to bromoxynil will utilize <1% of the RfD for the most highly exposed subpopulation, children 1-6 years old (discussed below). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Accordingly, EPA concludes that there is a reasonable certainty that no harm will result to the general population and major identifiable population subgroups from aggregate chronic exposure to bromoxynil.

D. Aggregate Cancer Risk for U.S. Population

The aggregate cancer risk for the U.S. population calculated for use of bromoxynil is 1.7 x 10^{-6}. EPA believes that a risk estimate of this level 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 x 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. Thus, EPA generally does not attach great significance to numerical estimates that differ by approximately a factor of 2. Therefore, EPA considers the

carcinogenic risk from bromoxynil to be negligible within the meaning of that standard as it has been traditionally applied by EPA. Accordingly, EPA concludes that there is a reasonable certainty that no harm will result to the general population and major identifiable population subgroups from aggregate exposure to bromoxynil. Specific risks to infants and children other than cancer are discussed below.

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

1. *Safety factor for infants and children*— i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of bromoxynil, EPA considered all available developmental and reproductive toxicity data. A total of 12 developmental and 3 reproductive toxicity studies were available for review. These include oral prenatal developmental toxicity studies (four in rats, two in rabbits, and one in mice with the phenol; one in rats with the octanoate), dermal prenatal developmental toxicity studies (one each in rats and rabbits with both the phenol and the octanoate), and dietary two-generation reproduction studies in rats (two with the phenol; one with the octanoate). The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database 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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Analysis.* Developmental toxicity was observed, following *in utero* exposure to bromoxynil, in multiple studies, by two routes of exposure, and in three species. The induction of supernumerary ribs was shown to be the most sensitive indicator of developmental toxicity in fetal rats, mice, and (in certain studies) rabbits. In EPA's 1997 tolerance action concerning bromoxynil (62 FR 33019, June 18, 1997), EPA concluded that the children's safety factor was not necessary to protect the safety of infants and children. That decision rested on the view that, given the large number of studies available on bromoxynil, EPA had a high degree of certainty regarding the level at which effects would occur in experimental animals. Since that action, EPA revisited the children's safety factor decision and concluded that the safety factor should be retained. This revised decision is based on EPA's conclusion that the standard 100-fold safety factor may not be adequate to protect the safety of infants and children given the clear showing of increased susceptibility of fetuses, the steep dose response curve, and the demonstrated severe developmental effects at doses above the LOEL. Nevertheless, EPA's decision at this time remains tentative due to the fact that EPA has only recently sought external science review of its approach to the children's safety factor and also instituted an internal reexamination process. Given the toxicological factors noted above, EPA is unwilling to make safety determinations regarding this pesticide without using the additional tenfold safety factor.

EPA believes that the population of concern for which the safety factor should be retained is the developing fetus and the endpoint of concern is supernumerary ribs. This endpoint, a developmental anomaly, results from *in utero* exposure. Although some systems in infants and children continue developing, it is unlikely that supernumerary ribs, even though observed across multiple species, would result from postnatal exposure. Since the acute dietary endpoint for females ≥13 years old is based on developmental effects, it was determined that the 10-fold safety factor should be applied to the acute risk assessment for females ≥13 years old (the population subgroup that is relevant to *in utero* exposure), but is not needed for children and infants. A 10-fold factor safety factor applied to females ≥13 years old will provide additional protection for infants and children and ensure a reasonable certainty of no harm to this sensitive subpopulation.

2. *Acute risk.* The MOE of >5,000 for children 1-6 years old, the most highly exposed subpopulation, is greater than the level of concern of 100. For females ≥13 years old, the population subgroup that is most relevant to the development of *in utero* exposure, the MOE of 11,000 is greater than the level of concern of 1000. Therefore acute risk for children does not trigger any concerns.

3. *Chronic risk.* Using the exposure assumptions described above, EPA has concluded that aggregate exposure to bromoxynil from food will utilize <1% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Therefore, the Agency concludes that there is a reasonable certainty of no harm to infants and children as a result of chronic dietary exposure to bromoxynil.

III. Other Considerations

A. Metabolism In Plants and Animals

The nature (metabolism) of bromoxynil residues in plants and livestock is adequately understood for the purposes of these tolerances. In all the plant and animal (poultry and ruminants) metabolism studies submitted, the residues of concern were parent bromoxynil and the metabolite DBHA. The tolerances for cotton commodities and livestock are expressed in terms of bromoxynil and DBHA.

Pending receipt of additional metabolism data for DBHA in livestock, the Agency has assumed that DBHA is of equal toxicity to the parent and translates proportionately to the parent for livestock commodities. The Agency believes these assumptions are adequately protective for purposes of these tolerances.

B. Analytical Enforcement Methodology

Adequate analytical methodology is available for data collection and tolerance enforcement for bromoxynil *per se* in plants. Method I in PAM, Vol. II, is a GLC/MCD that has undergone a successful EPA method validation on wheat grain. This method involves alkaline hydrolysis in methanolic KOH to convert residues to bromoxynil, cleanup by liquid-liquid partitioning, methylation using diazomethane, further cleanup on a Florisil column, and determination by GLC/MCD. Method Ia is the same method, but uses GC/ECD for determination of methylated bromoxynil.

The analytical method ''Bromoxynil: Method of Analysis for Bromoxynil and its Metabolite, 3,5-Dibromo-4-hydroxybenzoic Acid in Cottonseed, Gin Trash, and Seed Processed Fractions using GC-MSD.'' (Method RES9603) has been the subject of an Independent Laboratory Validation (ILV) and an Agency Petition Method Validation (PMV). The method validation data are being reviewed by the Agency; approval of the method for enforcement purposes is anticipated.

Method A is a GC/MCD or ECD method for the analysis of bromoxynil *per se* in livestock tissues and is essentially the same as Method I. Method B is a GC/ECD method that is also similar to Method I, with modifications to the cleanup procedures. A method for DBHA in animal commodities has been developed and is currently in the process of review and validation by the Agency.

C. Magnitude of Residues

In the petition for these tolerances, the registrant requested that 40 CFR 180.324 be amended by establishing tolerances for residues of the herbicide bromoxynil and its metabolite DBHA on cotton at 7 ppm for undelinted cottonseed, 50 ppm for cotton gin byproducts, and 21 ppm for cotton hulls. These proposed tolerances are the same as those issued in the June 18, 1997 final rule (62 FR 33019). Immediately prior to establishing these tolerances, the registrant reduced the maximum label rate as a result of Agency risk concerns. The tolerances were determined by extrapolating from residue studies conducted at the former maximum label rate (4.5 lb ai/A). Following the submission of the tolerance petition, the registrant submitted residue data for bromoxynil and DBHA in cotton commodities at the revised maximum application rate of 3 applications at 0.5 lb ai/A each for a total of 1.5 lb ai/A. These data show that bromoxynil and DBHA residues in cotton commodities are lower than the values determined for the June 18, 1997 final rule. Based on the new residue data, tolerances for bromoxynil and DBHA in cotton commodities are being changed to 7.0 ppm in cotton gin byproducts, 5.0 ppm in cotton hulls, and 1.5 ppm in undelinted cottonseed.

In the June 18, 1997 final rule, tolerances for livestock commodities (including milk and eggs) were expressed as bromoxynil per se only; the Agency concluded that measurement of bromoxynil per se in livestock commodities could serve as a marker to indicate the amount of DBHA present in livestock. After further consideration, the Agency has determined that measurement of bromoxynil per se in livestock is not adequate to determine the amount of DBHA present. Therefore, in this action, tolerances are expressed as bromoxynil and DBHA instead of only as bromoxynil per se in livestock.

Tolerances for ruminant commodities (meat, fat, and meat by products) were recalculated since issuing the June 18, 1997 final rule due to new information. First, new residue data for bromoxynil and DBHA in cotton commodities were used to determine expected maximum theoretical dietary exposure to bromoxynil and DBHA via ingestion of cotton commodities. Second, maximum theoretical residues in livestock commodities were recalculated based on a revision in the dosing levels used in livestock feeding studies. Doses were previously calculated in terms of bromoxynil octanoate; however, since tolerances in RACs (raw agricultural commodities) are for bromoxynil per se, doses were recalculated as such. Finally, changes were made to the relative contributions of feed items in the diet as a result of grazing restrictions for grass, and information provided by the registrant on the amount of cotton gin trash in beef and dairy cattle diets. These changes did not affect tolerances for residues in milk, eggs, or meat and fat of ruminants and poultry; however, the tolerances for residues in meat by-products increased to 3.5 ppm for ruminants and to 0.3 ppm for poultry.

D. International Residue Limits

There are no established or proposed Codex MRLs for bromoxynil residues.

E. Rotational Crop Restrictions

Required additional limited field rotational crop studies have not been submitted to the Agency; acceptable studies previously submitted in support of reregistration reflect a maximum seasonal and single application rate of 0.5 lb ai/A, but the use on cotton constitutes a maximum seasonal application rate of 1.5 lb ai/A. Pending receipt of these studies registered labels must restrict rotation of cotton fields treated at a rate of greater than 0.5 lb ai/A/season to cotton.

IV. Conclusion

Therefore, tolerances are established for bromoxynil and DBHA in undelinted cottonseed at 1.5 ppm, cotton gin byproducts at 7.0 ppm, and cotton hulls at 5.0 ppm. In addition, this document establishes tolerances for the residues of bromoxynil and DBHA, resulting from the application of octanoic and heptanoic acid esters of bromoxynil to cotton, in or on cattle, hogs, horses, goats, and sheep to 0.5 ppm in meat, 3.5 ppm in mbyp, and 1.0 ppm in fat. Further, this document establishes tolerances for residues of bromoxynil and DBHA, resulting from the application of octanoic and heptanoic acid esters of bromoxynil to cotton, at 0.1 ppm in milk; at 0.05 ppm in eggs; at 0.05 ppm in poultry meat and fat; and at 0.3 ppm in poultry mbyp.

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–300661] (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 Room 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 Hwy., 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 tolerances 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 1985, 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 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

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted 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 General Accounting Office prior to publication of this rule in today's **Federal Register**. This 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 6, 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. In § 180.324, paragraph (a) is revised to read as follows:

§ 180.324 Bromoxynil; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the herbicide bromoxynil (3,5-dibromo-4-hydroxybenzonitrile) resulting from application of its octanoic and/or heptanoic acid ester in or on the following commodities:

Commodity	Parts per million
Alfalfa, seeding	0.1 ppm
Barley, grain	0.1 ppm
Barley, straw	0.1 ppm
Corn, fodder (dry)	0.1 ppm
Corn, fodder (green)	0.1 ppm
Corn, fodder, field (dry)	0.1 ppm
Corn, fodder, field (green)	0.1 ppm
Corn, grain	0.1 ppm
Corn, grain, field	0.1 ppm
Flaxseed	0.1 ppm
Flax straw	0.1 ppm
Garlic	0.1 ppm
Grass, canary, annual, seed.	0.1 ppm
Grass, canary, annual, straw.	0.1 ppm
Mint hay	0.1 ppm
Oats, forage, green	0.1 ppm
Oats, grain	0.1 ppm
Oats, straw	0.1 ppm
Onions (dry bulb)	0.1 ppm
Rye, forage, green	0.1 ppm
Rye, grain	0.1 ppm
Rye, straw	0.1 ppm
Sorghum, fodder	0.1 ppm
Sorghum, forage	0.1 ppm
Sorghum, grain	0.1 ppm
Wheat, forage, green	0.1 ppm
Wheat, grain	0.1 ppm
Wheat, straw	0.1 ppm

(2) Tolerances are established for residues of the herbicide bromoxynil (3,5-dibromo-4-hydroxybenzonitrile) and its metabolite 3,5-dibromo-4-hydroxybenzoic acid (DBHA) resulting from application of its octanoic and/or heptanoic acid ester in or on the following commodities:

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

* * * * *

[FR Doc. 98–12639 Filed 5–8–98; 9:42 am]

BILLING CODE 6560–50–F

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.