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**Instructions:** Direct your comments to Docket ID No. EPA-R03-OAR-2006-0933. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [www.regulations.gov](http://www.regulations.gov) or e-mail. The [www.regulations.gov](http://www.regulations.gov) Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

**Docket:** All documents in the electronic docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Delaware Department of Natural Resources & Environmental Control, 89 Kings Highway, P.O. Box 1401, Dover, Delaware 19903.

**FOR FURTHER INFORMATION CONTACT:** Rosemarie Nino, (215) 814-3377, or by e-mail at [nino.rose@epa.gov](mailto:nino.rose@epa.gov).

**SUPPLEMENTARY INFORMATION:** For further information, please see the information provided in the direct final action, with the same title, that is located in the "Rules and Regulations" section of this **Federal Register** publication. This action approves an amendment to the Delaware Title V operating permit program to correct the definition of a "major source."

Dated: November 21, 2006.

**William T. Wisniewski,**  
*Acting Regional Administrator, Region III.*  
[FR Doc. E6-20642 Filed 12-5-06; 8:45 am]  
**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2006-0731; FRL-8104-1]

### Diphenylamine; Proposed Pesticide Tolerance

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

**ACTION:** Proposed rule.

**SUMMARY:** This document proposes to establish a tolerance for residues of diphenylamine in or on pear under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** Comments must be received on or before February 5, 2007.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2006-0731, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

**Instructions:** Direct your comments to docket ID number EPA-HQ-OPP-2006-

0731. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [www.regulations.gov](http://www.regulations.gov) or e-mail. The [www.regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

**Docket:** All documents in the docket are listed in the docket index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460-0001; telephone number: (703) 308-3194; e-mail address: [brothers.shaja@epa.gov](mailto:brothers.shaja@epa.gov).

**SUPPLEMENTARY INFORMATION:****I. General Information***A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through [www.regulations.gov](http://www.regulations.gov) or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

**II. Background and Statutory Findings**

EPA on its own initiative, under section 408(e) of the FFDCA, 21 U.S.C. 346a(e), is proposing to establish a tolerance for residues of the fungicide, diphenylamine in or on pear at 5.0 parts per million (ppm). The Interregional Research Project Number 4 (IR-4) submitted a petition (PP OE6107) for this use. However, neither IR-4 nor Atomchem North American Incorporated, the registrant, submitted all required elements of a petition in support of establishing a tolerance. Because the petition was incomplete, EPA did not publish a Notice of Filing for the petition.

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) of the FFDCA 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) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

**III. Aggregate Risk Assessment and Determination of Safety**

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for residues of diphenylamine on pear at 5.0 ppm. EPA's assessment of 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 diphenylamine is discussed in Table 1 of this unit as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents	NOAEL = 75 mg/kg/day LOAEL = 375 mg/kg/day based on decreased body weight and body weight gain, dark urine, increased absolute spleen and liver weights, congestion in spleen, kidney, and liver, discoloration and alterations in hematological and clinical chemistry parameters.
870.3100	90-Day oral toxicity rodents	NOAEL = 2 mg/kg/day M/F LOAEL = 94/107 mg/kg/day based on liver/spleen alterations (extramedullary hematopoiesis in the liver, discoloration and hemosiderosis of the liver, congestion and extramedullary hematopoiesis in the spleen).
870.3150	90-Day oral toxicity non-rodents	M/F NOAEL = 50 mg/kg/day LOAEL (mg/kg/day) not determined
870.3200	21/28-Day dermal toxicity	NOAEL = 500 mg/kg/day LOAEL = 1,000 mg/kg/day based on effects in the stomach (dark foci-red foci in both sexes-6/10). Dermal: NOAEL = 1,000 mg/kg/day; LOAEL (mg/kg/day): Not determined.
870.3700	Prenatal developmental in rodents	Maternal NOAEL = 50 mg/kg/day Maternal LOAEL = 100 mg/kg/day based on decreased spleen weights and discoloration of the spleen Developmental NOAEL = 100 mg/kg/day Developmental LOAEL (mg/kg/day): Not determined
870.3700	Prenatal developmental in nonrodents	Maternal NOAEL = 100 mg/kg/day Maternal LOAEL = 300 mg/kg/day based on decreased body weight gains and food consumption Developmental NOAEL = 300 mg/kg/day Developmental LOAEL (mg/kg/day): Not determined
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL (mg/kg/day): Not determined. Parental/Systemic M/F LOAEL = 40/46 mg/kg/day based on gross pathological findings in the spleen and microscopic findings in the kidney, liver, and spleen. Reproductive M/F NOAEL = 115/131 mg/kg/day. Reproductive M/F LOAEL = 399/448 mg/kg/day based on decreased litter size in both generations. Offspring M/F NOAEL = 40/46 mg/kg/day. Offspring M/F LOAEL = 115/131 mg/kg/day based on decreased body weight of F2 pups in late lactation.
870.4100	Chronic toxicity dogs	NOAEL = 10 mg/kg/day LOAEL = 50 mg/kg/day based on alterations in clinical chemistry parameters (increased BUN, cholesterol, total bilirubin) and increased absolute/relative kidney, liver and spleen weights.
870.4200	Carcinogenicity rats	NOAEL (mg/kg/day): Not determined. M/F LOAEL = 73/91 mg/kg/day based on histopathological lesions in the spleen. No evidence of carcinogenicity.
870.4300	Carcinogenicity mice	M/F NOAEL = 29/25 mg/kg/day. M/F LOAEL = 147/138 mg/kg/day based on reduced body weight and body weight gains, changes in hematological parameters, spleen and kidney lesions and increased clinical signs of toxicity. No evidence of carcinogenicity
870.5100	Gene mutation	Negative
870.5300	Cytogenetics	Weakly mutagenic in the presence of metabolic activation
870.5395	Other effects	Negative

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.7485	Metabolism and pharmacokinetics	<p>Terminal distribution data showed no significant residual activity in tissues 168 hours post-dose for both the low and high oral dose groups: Urine was the major route for excretion.</p> <p>Recovery after 168 hours: Single/repeated low dose = urine 68-81% (both sexes) single high dose = 73-74%</p> <p>Male rats excreted a greater percentage of diphenylamine derived activity at the low dose, while female rats showed greater excretion in feces at this dose. At the high dose, the percentage eliminated in urine was equivalent in both males and females.</p> <p>Metabolites-urine: Dihydroxylated conjugates of diphenylamine, mono-hydroxylated sulfate conjugates of diphenylamine, monohydroxylated glucuronide conjugates of diphenylamine.</p> <p>Metabolites-feces: Parent chemical and 4-hydroxydiphenylamine, which comprised 0.5-3% administered dose in both sexes.</p>

### B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where

the RfD is equal to the NOAEL divided by the appropriate UF ( $RfD = NOAEL / UF$ ). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor (SF).

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) =  $NOAEL / \text{exposure}$ ) is calculated and compared to the LOC.

The linear default risk methodology ( $Q^*$ ) is the primary method currently used by the Agency to quantify carcinogenic risk. The  $Q^*$  approach

assumes that any amount of exposure will lead to some degree of cancer risk. A  $Q^*$  is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as  $1 \times 10^6$  or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a “point of departure” is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ( $MOE_{\text{cancer}} = \text{point of departure} / \text{exposures}$ ) is calculated. A summary of the toxicological endpoints for diphenylamine used for human risk assessment is shown in Table 2 of this unit:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DIPHENYLAMINE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13-50 years of age)	N/A	N/A	An acute reference dose for females aged 13-50 has not been established. Developmental toxicity studies in rats and rabbits and a 2-generation reproduction study in rats did not demonstrate evidence of toxicity attributable to a single dose.
Acute Dietary (General population including infants and children)	N/A	N/A	An endpoint attributable to a single dose was not identified from the available database.
Chronic Dietary (All populations)	NOAEL = 10 mg/kg/day UF = 100 Chronic RfD = 0.1 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD/FQPA SF = 0.1 mg/kg/day	Chronic Toxicity - Dog LOAEL = 50 mg/kg/day based on alterations in clinical chemistry parameters (increased BUN, cholesterol, total bilirubin) and increased absolute/relative kidney, liver, and spleen weights.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DIPHENYLAMINE FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Short-Term Dermal (1 to 30 days) (Residential)	Dermal (or oral) study NOAEL = 500 mg/kg/day	LOC for MOE = 100 (Residential)	21-Day Dermal - Rabbit LOAEL = 1,000 mg/kg/day based on effects in the stomach (dark red foci in both sexes).
Intermediate-Term Dermal (1 week to several months) (Residential)	Dermal (or oral) study NOAEL = 500 mg/kg/day	LOC for MOE = 100 (Residential)	21-Day Dermal- Rabbit LOAEL = 1,000 mg/kg/day based on effects in the stomach (dark red foci in both sexes).
Short-Term Inhalation (1 to 30 days) (Residential)	Inhalation (or oral) study NOAEL = 50 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Developmental Toxicity - Rat LOAEL = 100 mg/kg/day based on increased spleen weights and discoloration of the spleen.
Intermediate-Term Inhalation (1 week to several months) (Residential)	Inhalation (or oral) study NOAEL = 50 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	Developmental Toxicity - Rat LOAEL = 100 mg/kg/day based on increased spleen weights and discoloration of the spleen.
Cancer (oral, dermal, inhalation)	N/A	N/A	Classification: This chemical is “not likely” to be a human carcinogen.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* The residue of concern in plants and livestock for the tolerance enforcement and risk assessment is parent diphenylamine. Tolerances are established in 40 CFR 180.190(a) for diphenylamine residues in/on apple at 10 ppm and apple, wet pomace at 30 ppm. Diphenylamine (EC or SC/L) is applied to apples (pre- or post-harvest) as a spray, dip or drench application. Additionally, tolerances are established at 0.01 ppm in milk, meat, fat, and meat byproducts (except liver) of cattle, goat, horse, and sheep, and at 0.1 ppm in liver of these animals. Risk assessments were conducted by EPA to assess dietary exposures from diphenylamine in food as follows:

i. *Acute exposure.* There were no toxic effects attributable to a single dose. An endpoint of concern was not identified to quantitate an acute-dietary risk to the U.S. general population or to the subpopulation females 13-50 years old. Therefore, an acute aggregate exposure assessment was not performed.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure

assessments: The chronic dietary exposure analysis was based on tolerance level residues, DEEM (Version 7.81) default processing factors, an empirical processing factor for apple juice, and 100% crop treated assumptions.

iii. *Cancer.* Diphenylamine was classified as “not likely to be a human carcinogen;” therefore, a cancer dietary exposure analysis was not performed.

2. *Dietary exposure from drinking water.* Diphenylamine uses are post-harvest; therefore, residues in drinking water are not relevant to this risk assessment.

3. *Dietary exposure from non-dietary exposure.* Diphenylamine is not registered for use on any sites that would result in residential exposure. Therefore a residential exposure risk assessment was not performed.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA 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.”

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to diphenylamine and any other substances and diphenylamine 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 diphenylamine has a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA’s website at <http://www.epa.gov/pesticides/cumulative/>.

### D. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure 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.

2. *Prenatal and postnatal sensitivity.* There is no indication of increased sensitivity of rats or rabbits to *in utero* and postnatal exposure to diphenylamine. In prenatal

developmental toxicity studies in rats and rabbits, no evidence of developmental toxicity was observed. In a 2-generation reproduction study, offspring toxicity (decreased body weight) was seen only in the presence of maternal toxicity.

3. *Conclusion.* EPA recommended the FQPA safety factor be reduced to 1X for the following reasons:

- i. There is a complete toxicity data base for diphenylamine;
- ii. The toxicity database showed no increase in susceptibility in fetuses and pups with in *utero* and postnatal exposure, and
- iii. The dietary food exposure assessment is based on recommended tolerance-level residues (except those processed commodities for which processing factors were used) and assumes 100% crop treated for all commodities, which resulted in very high-end estimates of dietary exposure.

#### *E. Aggregate Risks and Determination of Safety*

1. *Acute risk.* There were no toxic effects attributable to a single dose. An endpoint of concern was not identified to quantitate an acute-dietary risk to the U.S. general population or to the subpopulation females 13-50 years old. Therefore, diphenylamine is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to diphenylamine from food will utilize 12% of the cPAD for the U.S. population, 69% of the cPAD for all infants <1 year old, and 90% of the cPAD for children 1-2 years old. There are no residential uses for diphenylamine that result in chronic residential exposure. In addition, there is no potential for chronic dietary exposure in drinking water as diphenylamine is applied only as a post-harvest use. Therefore, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. *Short and intermediate-term risk.* There are no residential uses for diphenylamine, and residues are not expected to occur in drinking water. Therefore, short and intermediate-term aggregate risk assessments were not performed.

4. *Aggregate cancer risk for U.S. population.* Diphenylamine is not likely to be carcinogenic to humans. Therefore, a cancer aggregate risk assessment was not performed.

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

from aggregate exposure to diphenylamine residues.

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

##### *A. Analytical Enforcement Methodology*

An adequate gas chromatography/mass-selective detector (GC/MSD) method is available for enforcing tolerances on apple commodities, and this method was used for data collection in the current post-harvest study. The method was adequately validated in conjunction with the sample analyses. A modification of this method was used in the pear analyses. Therefore, the Agency requires the registrant to submit an analytical reference standard of diphenylamine to the EPA National Pesticide Standards Repository. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### *B. International Residue Limits*

Codex MRLs have been established for the post harvest use of diphenylamine on pears. The MRL for pear is 5 ppm, and is the same as the recommended pear tolerance.

#### **V. Conclusion**

A tolerance is proposed for residues of diphenylamine in pear at 5.0 ppm.

#### **VI. Statutory and Executive Order Reviews**

This proposed rule establishes a tolerance under section 408(d) of the FFDCA 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). Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in*

*Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this proposed action will not have significant negative economic impact on a substantial number of small entities. Establishment of a tolerance legalizes the presence of a pesticide residue in a food. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This proposed rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this proposed rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 3175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the

Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

#### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 22, 2006.

**Donald R. Stubbs,**

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

Therefore, it is proposed that 40 CFR chapter I be 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 180.190 is amended by alphabetically adding a commodity to the table in paragraph (a) to read as follows:

#### § 180.190 Diphenylamine; tolerances for residues.

(a) \* \* \*

Commodity	Parts per million
* * * *	*
Pear (post harvest) .....	5.0
* * * *	*

[FR Doc. E6-20648 Filed 12-5-06; 8:45 am]

BILLING CODE 6560-50-S

#### FEDERAL COMMUNICATIONS COMMISSION

#### 47 CFR Chapter I

[CC Docket No. 01-92; DA 06-2339]

#### Developing a Unified Inter-carrier Compensation Regime

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule, extension of reply comment period.

**SUMMARY:** This document grants a motion requesting an extension of time to file reply comments on an intercarrier compensation reform plan, the “Missoula Plan.” The Order modifies the pleading cycle by extending the comment period in order to facilitate the development of a more substantive and complete record in this proceeding.

**DATES:** Submit reply comments on or before January 11, 2007.

**ADDRESSES:** You may submit comments, identified by CC Docket No. 01-92, by any of the following methods:

• **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.

• **Agency Web site:** <http://www.fcc.gov>. Follow the instructions for submitting comments on the Electronic Comment Filing System (ECFS) / <http://www.fcc.gov/cgb/ecfs/>.

• **E-mail:** To [victoria.goldberg@fcc.gov](mailto:victoria.goldberg@fcc.gov). Include CC Docket 01-92 in the subject line of the message.

• **Fax:** To the attention of Victoria Goldberg at 202-418-1567. Include CC Docket 01-92 on the cover page.

• **Mail:** Parties should send a copy of their filings to Victoria Goldberg, Pricing Policy Division, Wireline Competition Bureau, Federal Communications Commission, Room 5-A266, 445 12th Street, SW., Washington, DC 20554.

• **Hand Delivery / Courier:** The Commission’s contractor, Natek, Inc., will receive hand-delivered or messenger-delivered paper filings for the Commission’s Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002.

—The filing hours at this location are 8 a.m. to 7 p.m.

—All hand deliveries must be held together with rubber bands or fasteners.

—Any envelopes must be disposed of before entering the building.

—Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

**People with Disabilities:** To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an e-mail to [fcc504@fcc.gov](mailto:fcc504@fcc.gov) or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

**Instructions:** All submissions received must include the agency name and

docket number. All comments received will be posted without change to <http://www.fcc.gov/cgb/ecfs/>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Notice requesting comment on the Missoula Plan. 71 FR 45510, Aug. 9, 2006.

#### FOR FURTHER INFORMATION CONTACT:

Jennifer McKee, Wireline Competition Bureau, Pricing Policy Division, (202) 418-1530, or Victoria Goldberg, Wireline Competition Bureau, Pricing Policy Division, (202) 418-7353.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission’s Order released November 20, 2006. The complete text of the Order is available for inspection and copying during business hours at the FCC Reference Information Center, Portals II, 445 12th St., SW., Room CY-A257, Washington, DC 20554. The complete text of this document also may be purchased from the Commission’s copy contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room, CY-B402, Washington, DC 20554. The complete text may also be downloaded at: <http://www.fcc.gov>. By the Order, the Wireline Competition Bureau (WCB) grants a motion requesting an extension of the date for filing reply comments on an intercarrier compensation plan called the “Missoula Plan.” The Missoula Plan was filed on July 24, 2006 by the National Association of Regulatory Utility Commissioners’ Task Force on Intercarrier Compensation. On July 25, 2006, the WCB released a Public Notice requesting that comments on the Missoula Plan be filed by September 25, 2006, and reply comments by November 9, 2006. 71 FR 45510, Aug. 9, 2006. On August 29, 2006, WCB released an order granting extensions of the comment and reply comment filing dates to October 25, 2006 and December 11, 2006. 71 FR 54008, Sep. 13, 2006. Over 110 parties filed initial comments on or before October 25, 2006. On November 17, 2006, the National Association of Regulatory Utility Commissioners filed a motion requesting an extension of the reply comment date to January 11, 2007.

The WCB determined that providing additional time to file reply comments will facilitate the development of a more substantive and complete record in this proceeding. Although it is the policy of the Commission that extensions of time shall not be routinely granted, the WCB determined that given the number, length, and variety of initial comments, good cause exists to provide parties an extension of time, from December 11,