Air pollution control, Compliance plans, Electric utilities, Penalties, Reporting and recordkeeping requirements, Sulfur dioxide.

Dated: May 5, 1999.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 72—[AMENDED]

1. The authority citation for part 72 continues to read as follows:

Authority: 42 U.S.C. 7601 and 7651, *et seq.*

2. Section 72.2 is amended by:

a. Removing from the definition of ''Compliance subaccount'' the words ''by the unit'' whenever they appear and the word ''unit's'' after the words ''meeting the''; and

b. Removing from the definition of ''Current year subaccount'' the words ''by the unit'' and replacing the word ''its'' with the word ''the''.

3. Section 72.40 is amended by adding to paragraph (a)(1) the words '', or in the compliance subaccount of another affected unit at the same source to the extent provided in § 73.35(b)(3),'' after the words ''under § 73.34(c) of this chapter)''.

PART 73—[AMENDED]

4. The authority citation for part 73 continues to read as follows:

Authority: 42 U.S.C. 7601 and 7651, *et seq.*

5. Section 73.35 is amended by revising paragraph (a)(2) and adding paragraph (b)(3) to read as follows:

§ 73.35 Compliance.

(a) * * *

(2) Such allowance is:

(i) Recorded in the unit's compliance subaccount; or

(ii) Transferred to the unit's compliance subaccount, with the transfer submitted correctly pursuant to subpart D of this part for recordation in the compliance subaccount for the unit by not later than the allowance transfer deadline in the calendar year following the year for which compliance is being established; or

(iii) Held in the compliance subaccount of another affected unit at the same source in accordance with paragraph (b)(3) of this section.

(b) * * *

(3)(i) If, after the Administrator completes the deductions under paragraph (b)(2) of this section for all affected units at the same source, a unit would otherwise have excess emissions and one or more other affected units at the source would otherwise have unused allowances in their compliance subaccounts and available for such other units under paragraph (a)(1) and (a)(2)(i) and (ii) of this section for the year for which compliance is being established, the Administrator will notify in writing the authorized account representative. The Administrator will state that the authorized account representative may specify in writing which of such allowances to deduct up to the amount calculated as follows, in order to reduce the tons of excess emissions otherwise at the unit:

Maximum deduction from other units = 0.95 × Excess emissions if no deduction from other units

Where:

''Maximum deduction from other units'' is the maximum number of allowances that may be deducted for the year for which compliance is being established, for the unit otherwise having excess emissions, from the compliance subaccounts of other units at the same source, rounded to the nearest allowance.

''Excess emissions if no deduction from other units'' is the tons of excess emissions that the unit would otherwise have if no allowances were deducted for the unit from other units under this paragraph (b)(3)(i) or paragraph (b)(3)(ii) of this section.

(ii) Notwithstanding paragraph (b)(3)(i) of this section, if the amount calculated results in less than 10 tons of excess emissions, the maximum deduction from other units shall be adjusted so that 10 tons of excess emissions, or the tons of excess emissions that would result if no allowances could be deducted from other units, whichever is less, remain for the unit.

(iii) If the authorized account representative submits within 15 days of receipt of a notification under paragraph (b)(3)(i) of this section a written request specifying allowances to deduct in accordance with paragraphs (b)(3)(i) and (ii) of this section, the Administrator will deduct such allowances, and reduce the tons of excess emissions otherwise at the unit by an equal amount, up to the amount calculated under paragraphs (b)(3)(i) and (ii) of this section.

* * * * *

[FR Doc. 99–12007 Filed 5–12–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300773A; FRL–6077–3]

RIN 2070–AB78

Diphenylamine; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of diphenylamine in or on pears. IR-4 requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective May 13, 1999. Objections and requests for hearings must be received by EPA on or before July 12, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300773A], 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–300773A], 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, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@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–300773A]. 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: Pat Cimino, Office of the Director, (7501C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 1119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–308–9357, cimino.pat@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 19, 1999 (64 FR 8273) (FRL–6052–2), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing a proposed regulation to establish a time-limited tolerance for residues of diphenylamine on pears. This notice was initiated by the Agency and included a summary of the toxicological profile and safety findings of the Agency. There were no comments received in response to the notice of filing.

The proposed rule requested that 40 CFR 180.190 be amended by establishing a tolerance for residues of the plant growth regulator diphenylamine, in or on pears at 10 part per million (ppm).

I. Background and Statutory Findings

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

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

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 diphenylamine and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of diphenylamine on pears at 10 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by diphenylamine are discussed in this unit.

B. Toxicological Endpoints

1. *Acute toxicity*. For acute dietary exposure (1 day) a risk assessment is not required since no appropriate toxicity endpoint or no-observed adverse effect level (NOAEL) could be identified from the available data. No developmental toxicity was observed at any dose level in the test animals. The highest doses tested were 100 milligrams/kilogram/day (mg/kg/day) in rats and 300 (mg/kg/day) in rabbits.

2. *Short- and intermediate-term toxicity.* Short- and intermediate-term risk assessments take into account exposure from indoor and outdoor residential exposure plus chronic dietary food and water (considered to be a background exposure level). This risk assessment is not required because there are no indoor or residential uses for this pesticide. Risk from chronic dietary food and water toxicity endpoints and exposure is taken into account under the chronic exposure and risk section below.

3. *Chronic toxicity*. EPA has established the RfD for diphenylamine at 0.03 (mg/kg/day). This Reference Dose (RfD) is based on a chronic dog study with a lowest observed adverse effect level (LOAEL) of 10 mg/kg/day. An Uncertainty Factor (UF) of 100 was used to account for both the interspecies extrapolation and the intraspecies variability. An additional UF of three was recommended to account for the lack of a NOAEL and the Committee's concern with respect to potential methemoglobinemia which was not tested in this study.

It should be noted that although the LOAEL was established at 10 mg/kg/day, in both males and females (based on hematological and clinical chemistry changes, and clinical signs of toxicity), because of the lack of information on methemoglobinemia the LOAEL could not be verified and was considered tentative until this issue is addressed. The Agency has required that a subchronic study of sufficient duration be conducted in dogs to investigate this possible methemoglobinemic effect to accurately define the NOAEL in the critical study. This study has been initiated by the registrant.

This chemical has been reviewed by the FAO/WHO joint committee meeting on pesticide residue (JMPR) and an acceptable daily intake (ADI) of 0.02 mg/kg/day has been established by that Committee.

4. *Carcinogenicity*. The Agency classified diphenylamine as ''not likely'' in reference to carcinogenicity in April, 1997. This classification was based on the lack of evidence for carcinogenicity in the two acceptable carcinogenicity studies in either male or female CD-1 mice or Sprague-Dawley rats.

A nitrosamine impurity, diphenylnitrosamine, occurs in diphenylamine technical product. Diphenylnitrosamine is a quantified carcinogen. The technical product producer, Elf Atochem, has submitted nitrosamine data which confirms that the maximum total nitrosamine contamination expected for the diphenylamine technical would be 10 ppm. The Agency concluded that residue data depicting nitrosamine levels in pome fruits (apples and pears) would not be required, but that a nitrosamine level of 0.0001 ppm in apples and pears should be used in dietary risk assessments for diphenylamine.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.190) for the residues of diphenylamine, in or on a variety of raw agricultural commodities. These include apples, and cattle, goat, horse and sheep meat. Risk assessments were conducted by EPA to assess dietary exposures from diphenylamine as follows:

Section 408(b)(2)(E) authorizes EPA to use available data and information on

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

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 1–day or single exposure. An acute risk assessment is not required since no appropriate endpoint or NOAEL could be identified from the available data. No developmental toxicity was seen at any dose level in the test animals. The highest doses tested were 100 mg/kg/day in rats and 300 mg/kg/day in rabbits.

ii. *Chronic exposure and risk.* A Dietary Exposure Evaluation Model (DEEM) chronic exposure analysis was performed by the Agency using Anticipated Residue Concentration (ARC) for apples and Theoretical Maximum Residue Concentration (TMRC) for pears, meat and milk. Percent crop treated estimates were not used for the chronic risk assessment. Tolerances are currently established for apples at 10 ppm and for meat and milk at 0 ppm. The Agency has recommended that the following tolerances be established in the 1998 Registration Eligibility Document (RED) for diphenylamine: wet apple pomace (an animal feed item) at 30.0 ppm, milk at 0.01 ppm, meat except liver at 0.01 ppm, and meat liver at 0.10 ppm. The recommended tolerances are supported by data and the Agency, on its own initiative, is in the process of establishing these tolerances.

The Agency determined that 10 ppm is appropriate for diphenylamine residues in pears for a time-limited tolerance based on bridging data from the apple residue studies to pears. The use patterns are identical for apples and pears and the fruit are substantially similar. The TMRC level for apples, 10 ppm, was determined from field testing at maximum label rates and sampling immediately after treatment. The wet apple pomace residue value, 30 ppm, was derived from apple processing data using the highest average field trial residue value, 5.86 ppm, multiplied by the average concentration factor, 4.7x, observed in wet apple pomace. The meat and milk TMRC values recommended in the 1998 RED for diphenylamine were obtained from a ruminant feeding study which indicates that at 1x, 3x and 10x feeding rates (30 ppm, 90 ppm and 300 ppm diphenylamine) diphenylamine was detected in one or more meat, meat by-product or milk fractions.

The ARC for apples used in the DEEM chronic exposure analysis is 0.562 ppm and was obtained from USDA's Pesticide Data Program (PDP). The PDP program was designed by EPA and USDA to provide EPA with market basket type residue values for refined risk assessments. The PDP samples crop commodities from grocery store distribution centers for pesticide residue analysis in order to better determine the residues which occur in foods at the time consumers purchase them. The eighteenfold drop in tolerance values between the TMRC derived apple tolerance of 10 ppm compared to the ARC/PDP derived tolerance of 0.562 ppm represents the difference in tolerance levels at the ''farm gate'' (worst case tolerance levels measured immediately after harvest or in the case of diphenylamine, immediately after treatment) versus the tolerance level which occurs close to actual purchase time.

The proposed pear tolerance at the TMRC of 10 ppm, was used in the DEEM chronic exposure analysis to calculate the dietary contribution from pears. The addition of pears to the apple ARC and RED recommended tolerances for meat, milk and wet apple pomace represents 3.9% of the RfD for the general U.S. population, and 31.3% of the RfD for the most sensitive sub-population, non-nursing infants (< 1 year old). Diphenylamine is classified as ''not likely'' to be carcinogenic to humans via the relevant routes of exposure.

A dietary risk assessment for diphenylnitrosamine, an impurity in technical product diphenylamine, was calculated using the nitrosamine residue level of 0.0002 ppm (0.0001 ppm each for apples and pears). The Q* for diphenylnitrosamine is 4.9×10^{-3} as reported on IRIS. The DEEM chronic exposure analysis calculated an ARC for the total U.S. Population of 0.001155 mg/kg/day.

To calculate the cancer risk for the diphenylnitrosamine, multiply the ARC (0.001155 mg/kg/day) by 2.0×10^{-5} (because diphenylnitrosamine dietary contribution from apples and pears is 20 ppm or 20/1,000,000). Divide this result by 70 years to correct the average daily dose to a lifetime average daily dose. Finally, multiply this result by the Q* of 0.0049 mg/kg/day and the cancer risk is calculated to be 1.6×10^{-12}.

0.001155 mg/kg/day $\times 2.0 \times 10^{-5} = 2.3 \times 10^{-8}$

$2.3 \times 10^{-8}/70$ years $= 3.3 \times 10^{-10}$

$3.3 \times 10^{-10} \times 4.9 \times 10^{-3} = 1.6 \times 10^{-12}$ mg/kg/day

This value is well below the Agency's level of concern for nitrosamine in the diet.

2. *From drinking water.* Dietary risk from drinking water is assumed to be negligible because negligible exposure results from the pesticidal uses. The use pattern is limited to pome fruit drenches in fruit packing houses and there are no detections in the Agency's Pesticides in Ground water Database or the U.S. EPA's ''STORET'' database.

3. *From non-dietary exposure.* Diphenylamine is not currently registered for use on 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.''

EPA does not have, at this time, available data to determine whether diphenylamine 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, 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk.* An acute dietary risk assessment was not conducted since no appropriate endpoint or NOAEL could be identified from the available data. No developmental toxicity was observed at

any dose level in the test animals. The highest doses tested were 100 mg/kg/day in rats and 300 mg/kg/day in rabbits.

2. *Chronic risk.* Using the ARC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to diphenylamine from food will utilize 3.9% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants and is 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.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account indoor and outdoor residential exposure plus chronic dietary food and water (considered to be a background exposure level). A short- and intermediate-term risk assessment is not required as there are no indoor or outdoor residential uses for this pesticide and chronic exposure is accounted for above.

4. *Aggregate cancer risk for U.S. population.* Diphenylamine is classified as ''not likely'' to be carcinogenic to humans via the relevant routes of exposure.

A dietary risk assessment for diphenylnitrosamine, the impurity in diphenylamine, was calculated using the nitrosamine residue level of 0.0001 ppm each for apples and pears. The Q* for diphenylnitrosamine is 4.9×10^{-3} as reported on IRIS. The chronic DEEM analysis calculated an ARC for the total U.S. population of 0.001155 mg/kg/day. Using these values, the cancer risk is calculated to be 1.6×10^{-12}. This value is well below the Agency's level of concern for nitrosamine in the diet.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to diphenylamine residues.

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 diphenylamine, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (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. *Developmental toxicity studies.* In a developmental toxicity study, pregnant female Sprague-Dawley rats (25/group) received diphenylamine (99.9%) in corn oil by oral gavage at dose levels of 0, 10, 50, or 100 mg/kg/day from gestation day 6 through gestation day 15 inclusive; dams were sacrificed on gestation day 20. None of the rats died during the study. Maternal toxicity was evidenced by increased splenic weights, enlarged spleens and blackish-purple colored spleen in the dams at 100 mg/kg/day. The maternal toxicity NOAEL was 50 mg/kg/day and the LOAEL was 100 mg/kg/day. No developmental toxicity was seen at any dose level. The developmental toxicity NOAEL was equal to or greater than 100 mg/kg/day the highest dose tested (HDT); a LOAEL was not established.

In a developmental toxicity study, pregnant New Zealand White rabbits received either 0, 33, 100, or 300 mg/kg/day diphenylamine (99.9%) suspended in 1% methyl cellulose by oral gavage from gestation day 7 through 19, inclusive. Animals came from 3 sources (vendors). Maternal toxicity was noted at 300 mg/kg as decreases in food consumption and associated initial reductions in body weight gain. The maternal toxicity NOAEL was 100 mg/kg/day and the LOAEL was 300 mg/kg/day based on decreased body weight gains and food consumption early during the treatment period. No developmental toxicity was noted at any dose level. The developmental toxicity NOAEL was equal to or greater than 300 mg/kg/day (HDT); a LOAEL was not established.

iii. *Reproductive toxicity study.* In a 2-generation reproductive toxicity study, Sprague-Dawley rats (28 per sex/group) received diphenylamine (99.8%) in the diet at dose levels of 0, 500, 1,500, or 5,000 ppm (0, 40, 115, or 399 mg/kg/day for F_0 males and 0, 46, 131, or 448 mg/kg/day for F_0 females, respectively, during premating). Compound-related systemic toxicity was observed in a dose related manner among both sexes and generations at all dose levels. The systemic toxicity NOAEL was less than 500 ppm (40 mg/kg/day in males and 46 mg/kg/day in females) and the LOAEL was less than or equal to 500 ppm based on gross pathological findings in the kidney, liver, and spleen. Developmental toxicity was observed at 1,500 and 5,000 ppm, as evidenced by significantly decreased body weight for F_1 pups at 5,000 ppm throughout lactation (11% to 25 % less than control), for F_2 pups at 5,000 ppm from lactation day (LD) 4 through LD 21 (10% to 29% less than control), and for F_2 pups at 1,500 ppm on LD 14 (10%) and LD 21 (12%). The developmental toxicity NOAEL was 500 ppm (46 mg/kg/day for maternal animals) and the LOAEL was 1,500 ppm (131 mg/kg/day for maternal animals) based on decreased F_2 pup body weight in late lactation. In a two-generation reproductive toxicity study, Sprague-Dawley rats (28 per sex/group) received diphenylamine (99.8%) in the diet at dose levels of 0, 500, 1,500, or 5,000 ppm (0, 40, 115, or 399 mg/kg/day for F_0 males and 0, 46, 131, or 448 mg/kg/day for F_0 females, respectively, during premating). Compound-related systemic toxicity was observed in a dose related manner among both sexes and generations at all dose levels. The systemic toxicity NOAEL was less than 500 ppm (40 mg/kg/day in males and 46 mg/kg/day in females) and the LOAEL was less than or equal to 500 ppm based on gross pathological findings in the kidney, liver, and spleen. Developmental toxicity was observed at 1,500 and 5,000 ppm, as evidenced by significantly decreased body weight for F_1 pups at 5,000 ppm throughout lactation (11% to 25 % less than control), for F_2 pups at 5,000 ppm from lactation day (LD) 4 through LD 21 (10% to 29% less than control), and for F_2 pups at 1,500 ppm on LD 14 (10%) and LD 21 (12%). The developmental toxicity NOAEL was 500 ppm (46 mg/kg/day for maternal animals) and the LOAEL was 1,500 ppm (131 mg/kg/day

for maternal animals) based on decreased F_2 pup body weight in late lactation. Reproductive toxicity was noted as smaller litter sizes at birth (significant for the F_2 litters) in both generations at 5,000 ppm. The reproductive toxicity NOAEL was 1,500 ppm (131 mg/kg/day for maternal animals) and the LOAEL was 5,000 ppm (448 mg/kg/day for maternal animals), based upon decreased litter size in both generations.

iv. *Pre- and post-natal sensitivity.* For purposes of assessing the pre- and post-natal toxicity of diphenylamine, EPA has evaluated two developmental and one reproduction study. Based on current toxicological data requirements, the data base for diphenylamine, relative to pre- and post-natal toxicity is complete. However, as EPA fully implements the requirements of FQPA, additional data related to the special sensitivity of infants and children may be required.

The data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to diphenylamine. The reproduction study demonstrated that the offspring were less sensitive than the adults and there was no developmental toxicity observed in either the rat or rabbit developmental studies at any dose tested.

v. *Conclusion.* There is a complete toxicity data base for diphenylamine and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

2. *Acute risk.* An acute dietary risk assessment was not conducted since no appropriate endpoint or NOAEL could be identified from the available data. No developmental toxicity was observed at any dose level in the test animals. The highest doses tested were 100 mg/kg/day in rats and 300 mg/kg/day in rabbits.

3. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to diphenylamine from food will utilize 31.3 percent 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. Exposure is from food only as drinking water exposure is considered negligible and there are no residential uses and consequently no exposure from non-dietary, non-occupational uses of this pesticide.

4. *Short- or intermediate-term risk.* Short- or intermediate-term non-dietary, non-occupational exposure scenarios do not exist for diphenylamine and a short- or intermediate-term aggregate risk assessment is not required.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to diphenylamine residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The qualitative nature of the residue in plants and livestock is adequately understood based on acceptable apple, ruminant and poultry metabolism studies. The Agency has concluded that the residue of concern in plants and livestock is diphenylamine per se.

B. Analytical Enforcement Methodology

The Food and Drug Administration (FDA) PESTDATA database dated 1/94 (Pam Vol. I, Appendix I) indicates that diphenylamine is completely recovered using FDA Multiresidue Protocol D (PAM I Section 232.4). In addition, a gas chromatography (GC)/mass selective detection (MSD) method is available for the quantitation of diphenylamine residues in apples which should be bridgeable to pears.

Adequate enforcement methodology (example - gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

C. Magnitude of Residues

For the purposes of this time-limited tolerance, apple data have been used to estimate the magnitude of residues on pears. The use patterns for apples and pears are identical and the fruit types are substantially similar. Adequate magnitude of the residue data are available to support the use on apples. Acceptable residue data depicting diphenylamine residues in apples following a single posttreatment application at the maximum use rate have been submitted, and indicate that the existing 10 ppm tolerance for diphenylamine residues in apples is also appropriate for pears.

D. International Residue Limits

There are no international residue limits established for diphenylamine on pears.

E. Rotational Crop Restrictions

Rotational crop restrictions do not apply for two reasons: (1) Diphenylamine is used indoors only in fruit packing houses as a postharvest drench treatment to control scald; and (2) pears are a perennial crop and are not subject to rotational crop restrictions.

IV. Conclusion

Numerous residues of diphenylamine have been detected on pears, a use which is not registered and does not have an established tolerance, by the United States Department of Agriculture's (USDA) Pesticide Data Program (PDP) in both domestic and foreign pears due to inadvertent transfer of diphenylamine residues from apples to pears during packing. Public reporting of PDP food residue monitoring occurred earlier this year and in order to prevent public concern regarding residues of diphenylamine in pears the Agency assessed the aggregate risk from exposure on pears, found it acceptable, and proposed to establish a time-limited tolerance for this use on February 19, 1999. No comments were received during the 15–day comment period.

The U.S. pear industry has asked the IR-4 program and pesticide registrants to generate the reports and data required to support the establishment of a tolerance and registration of diphenylamine on pears. The data generation have been initiated and the Agency expects these data to be submitted in 2 years. In the meantime, the Agency has assessed the risk from this use on pears based on bridging data from apples to pears and found that a reasonable certainty of 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. Therefore, a time-limited tolerance is established for residues of diphenylamine in pears at 10 ppm, the same level as currently established on apples, which will expire on December 1, 2001.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation 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 12, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this regulation. 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). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James 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: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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 Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300773A] (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.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit 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 record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final 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). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

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

governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

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

C. Executive Order 13084

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

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

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: April 30, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.190 is revised to read as follows:

§ 180.190 Diphenylamine; tolerances for residues.

(a) *General.* Tolerances for the residues of the plant growth regulator diphenylamine are established as follows:

Commodity	Parts per million
Apple, preharvest or postharvest, including wraps	10
Cattle, meat	0
Goat, meat	0
Horse, meat	0
Sheep, meat	0

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

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

(d) *Indirect or inadvertent residues.* A time-limited tolerance is established for the indirect or inadvertent residues of diphenylamine in or on the following commodity:

Commodity	Parts per million	Expiration/ Revocation Date
Pears	10	12/1/01

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