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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this 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 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 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). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, 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. 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 final 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 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 13175, 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 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 rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801*et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final 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: July 31, 2003.

Debra Edwards,

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), 346(a) and 371.

■ 2. Section 180.548 is amended by revising the table to paragraph (a) to read as follows:

§ 180.548 Tralkoxydim; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration/ revocation date
Barley, grain	0.02	5/1/05
Barley, hay	0.02	5/1/05
Barley, straw	0.05	5/1/05
Wheat, forage	0.05	5/1/05
Wheat, grain	0.02	5/1/05
Wheat, hay	0.02	5/1/05
Wheat, straw	0.05	5/1/05

* * * * *

[FR Doc. 03–20433 Filed 8–12–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0251; FRL–7319–5]

Hydramethylnon; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of hydramethylnon in or on pineapple. BASF requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 13, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0251, must be received on or before October 14, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Richard J. Gebken, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–6701; e-mail address: *gebken.richard@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 111)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)
- Animal production (NAICS 112)

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. 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. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0251 The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of October 6, 1999 (64 FR Page 54300–54303) (FRL–6029–9), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 2F02609) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709–3528. That notice included a summary of the petition prepared by BASF Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.395 be amended by establishing a tolerance for residues of the insecticide Hydramethylnon in or on pineapple at 0.05 parts per million (ppm).

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* the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

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 hydramethylnon on pineapple at 0.05 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 hydramethylnon are 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	Subchronic Feeding - Rat	NOAEL = 2.5 mg/kg/day LOAEL = 5.0 mg/kg/day - decreased testicular weights (34%), and testicular atrophy.
870.3150	Subchronic Gavage - Dog	NOAEL = 3 mg/kg/day - LDT; decreased food consumption (11%/20%, males/females) and body weight gain (11%/9%, males/females). LOAEL = not defined Lethal Dose = 6 mg/kg/day - decreased food consumption and body weight gain, ↑SGPT, cachexia, wasting of muscle and subcutaneous fat, testicular atrophy, and death.
870.3150	Subchronic Gavage - Dog	NOAEL = 1.0 mg/kg/day LOAEL = 3.0 mg/kg/day - increased incidence of soft stools, mucoid stools, and diarrhea.
870.3200	21–Day Dermal - Rabbit	NOAEL = 250 mg/kg/day (HDT) Food consumption was depressed as much as 38% and 45% in the high-dose males and females, compared to controls. The high-dose males and females weighed as much as 8% and 9% less than the controls. The platelet count in the high-dose females at termination was 54% less than controls, but was not considered adverse because it is a common finding following skin abrasion.
870.3700	Developmental Toxicity - Rat	Maternal NOEL = 3 mg/kg/day Maternal NOAEL = 10 mg/kg/day - 8% decrease in body weight and yellowish discoloration of the fat. Maternal LOAEL = 30 mg/kg/day - 16% decrease in body weight; increased incidence of nasal mucus, alopecia, soft stools, staining of the anogenital fur, yellowish discoloration of the fat, and small thymus. Developmental NOEL = 10 mg/kg/day Developmental LOAEL = 30 mg/kg/day - decreased mean fetal weights and increased incidence of rudimentary structures and incompletely ossified supraoccipitals. At 30 mg/kg/day, a 16% decrease in maternal body weight, increased incidence of clinical signs (nasal mucus, alopecia, soft stool, staining of anogenital fur), yellowish discoloration of the fat, and small thymus were observed.
870.3700	Developmental Toxicity - Rabbit	Maternal NOAEL = 5 mg/kg/day - soft stools, and reduced amount of stools. Maternal LOAEL = 10 mg/kg/day - abortions, soft stools, reduced amount of stools, and anogenital matting and discharge. Developmental NOAEL = 5 mg/kg/day - decreased fetal weight (8%). Developmental LOAEL = 10 mg/kg/day - abortions, decreased fetal weight (16%).
870.3800	2-Generation Reproductive Toxicity - Rat	Reproductive/Systemic NOAEL = 25 ppm (1.66/2.01 mg/kg/day, male/female) Reproductive/Systemic LOAEL = 50 ppm (3.32 / 4.13 mg/kg/day, male/female) (degeneration of the germinal epithelium (1/29) and aspermia (1/29)
870.4100	Chronic Feeding Toxicity - Dog	*See* 870.3150
870.4200	Carcinogenicity Feeding - Mouse (18 months)	NOAEL = 25 ppm (3.57 mg/kg/day) in males NOAEL = not defined in females. LOAEL = 50 ppm (6.93 mg/kg/day) in males (testicular lesions) LOAEL = 25 ppm (4.45 mg/kg/day) in females (LDT; combined lung adenomas and carcinomas) The high-dose females were sacrificed after 5 weeks due to high mortality.

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

Guideline No.	Study Type	Results
870.4300	Chronic Feeding Toxicity/Carcinogenicity-Rat	NOAEL = 50 ppm (2.4 mg/kg/day in males, 3.0 mg/kg/day in females) LOAEL = 100 ppm (4.9 mg/kg/day in males, 6.2 mg/kg/day in females) (small, soft testes, decreased testicular weights, and testicular atrophy in males; decreased body weight gain in females)
870.5100	Bacterial Reverse Mutation Test (Ames Assay)	Negative
870.5375	*In Vitro* Chromosomal Aberration in Chinese Hamster Ovary (CHO) Cells	Negative
870.5450	Rodent Dominant Lethal Assay - Rat	Negative
870.5575	D4 Mitotic Gene Conversion Assay	Negative
	P1 Forward Gene Mutation Assay	Negative
870.7485	Metabolism - Rat	The majority of the administered dose of phenyl- or pyrimidinyl- ^{14}C-CI 217,300 was recovered in the feces (85–98%). Recovery in the urine was minimal (1- to 2% of the administered dose). There were no sex or dose-related differences in urinary or fecal elimination.
870.7600	Dermal Penetration - Rat	Sprague-Dawley rats were dermally dosed with a gel formulation containing 2% a.i. (Maxforce Gel®). Total dose absorbed after 10 hours was 0.414%
870.7600	Dermal Penetration - Rat	Sprague-Dawley rats were dermally dosed with a gel formulation containing 2.16% a.i. (Siege®). Total dose absorbed after 10 hours was 0.97%

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 factors (SF) 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 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/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 x 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_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for hydramethylnon used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR HYDRAMETHYLNON 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)	NOAEL = 5 mg/kg/day UF = 100 Acute RfD = 0.05 mg/kg/day	FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF = 0.05 mg/kg/day	Developmental toxicity in rabbits LOAEL = 10 mg/kg/day based on abortions.
Acute Dietary (General population including infants and children)	-	-	There is no appropriate single dose endpoint for the general population.
Chronic Dietary (All populations)	NOAEL= 1.66 mg/kg/day UF = 100 Chronic RfD = 0.017 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD ÷ FQPA SF = 0.017 mg/kg/day	2-Generation reproductive toxicity in rats LOAEL = 3.32 mg/kg/day based on testicular effects.
Short-Term Incidental Oral (1–30 days)	Oral NOAEL= 1.66 mg/kg/day	LOC for MOE = 100 (Residential)	2-Generation reproductive toxicity in rats LOAEL = 3.32 mg/kg/day based on testicular effects.
Intermediate-Term Incidental Oral (1–6 months)	Oral NOAEL= 1.66 mg/kg/day	LOC for MOE = 100 (Residential)	2-Generation reproductive toxicity in rats LOAEL = 3.32 mg/kg/day based on testicular effects.
Short-Term Dermal (1 to 30 days)(Residential)	Oral NOAEL= 1.66 mg/kg/day (dermal absorption rate = 1%)	LOC for MOE = 100 (Residential)	2-Generation reproductive toxicity in rats LOAEL = 3.32 mg/kg/day based on testicular effects.
Intermediate-Term Dermal (1 week to 6 months) (Residential)	Oral NOAEL = 1.66 mg/kg/day(dermal absorption rate = 1%)	LOC for MOE = 100 (Residential)	2-Generation reproductive toxicity in rats LOAEL = 3.32 mg/kg/day based on testicular effects.
Long-Term Dermal (several months to lifetime) (Residential)	Oral NOAEL= 1.66 mg/kg/day (dermal absorption rate = 1%)	LOC for MOE = 100 (Residential)	2-Generation reproductive toxicity in rats LOAEL = 3.32 mg/kg/day based on testicular effects.
Short-Term Inhalation (1 to 7 days) (Residential)	inhalation (or oral) study NOAEL= 1.66 mg/kg/day(inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	2-Generation reproductive toxicity in rats LOAEL = 3.32 mg/kg/day based on testicular effects.
Intermediate-Term Inhalation (1 week to several months) (Residential)	inhalation (or oral) study NOAEL = 1.66 mg/kg/day(inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	2-Generation reproductive toxicity in rats LOAEL = 3.32 mg/kg/day based on testicular effects.
Long-Term Inhalation (several months to lifetime) (Residential)	inhalation (or oral) study NOAEL= 1.66 mg/kg/day(inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	2-Generation reproductive toxicity in rats LOAEL = 3.32 mg/kg/day based on testicular effects.
Cancer (oral, dermal, inhalation)	The Agency's Cancer Peer Review Committee determined that hydramethylnon should be classified as a Group C-possible human carcinogen, and recommended that, for the purpose of risk characterization, the Reference Dose approach should be used for quantification of human risk. The Cancer Peer Review report was issued on March 28, 1991. The Agency's HIARC committee concurred with the cancer classification on March 4, 2003.		

*The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.395) for the residues of hydramethylnon, on grass and grass hay for pasture and rangeland at 0.05 ppm established in terms of parent only, tetrahydro-5,5-dimethyl-2(1H)-pyrimidinone (3-(4-(trifluoromethyl)phenyl)-1-(2-(4-(trifluoromethyl)phenyl)ethenyl)-2-propenylidene) hydrazone. The Agency determined that the residue of concern in grasses and the milk, meat, and meat byproducts of ruminants is hydramethylnon per se, and that there is no reasonable expectation of finite hydramethylnon residues of concern in

the milk, meat, and meat byproducts of ruminants 40 CFR 180.6(a)(3) as a result of hydramethylnon use on grasses. The Agency has also previously recommended that the grass forage tolerance be increased to 2.0 ppm and the grass hay tolerance be increased to 0.1 ppm. The residue chemistry and toxicological databases support the requested tolerance of 0.05 ppm for hydramethylnon on pineapple. Since there are no detectable hydramethylnon residues in the pineapple feed item, process residues, tolerances for hydramethylnon residues in animal commodities need not be established. Risk assessments were conducted by EPA to assess dietary exposures from hydramethylnon in food as follows:

i. *Acute exposure*. 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. An unrefined, Tier 1 acute dietary exposure assessment was conducted using tolerance-level residues and assuming 100% crop treated (CT) for all registered and proposed commodities. The acute analysis was conducted for females 13–49 years old only as no appropriate single dose endpoint was established for the general U.S. population and infants and children.

The acute dietary exposure estimates are well below the Agency's level of concern (<100% aPAD) at the 95th exposure percentile for females 13–49 years old (<1% of the aPAD).

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 1994–1996/1998 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: A Tier 1 (conservative, deterministic assessment using tolerance-level residues, and 100% crop treated (CT) for the proposed commodity; and DEEM-FCID® ver. 1.30, processing factors set to (1) a chronic dietary exposure assessment was conducted for the general U.S. population and various population subgroups. The chronic dietary exposure estimates are well below the Agency's level of concern (<100% cPAD) for the general U.S. population (<1% of the cPAD) and all population subgroups.

iii. *Cancer*. In a chronic feeding/carcinogenicity study in Charles River CD rats, no compound-related clinical signs were observed and survival was not affected by treatment. The LOAEL was based on small, soft testes, decreased testicular weights (27%), and testicular atrophy in males; and decreased body weight gain in females (22%). Statistically significant findings of neoplasia were found in the uterus (adenomatous polyps) and adrenals (medullary adenomas), but these were not considered toxicologically significant because they were seen at doses above the MTD.

In an 18 month carcinogenicity feeding study in Charles River CD-1 mice, survival decreased as the dose increased, but not enough to jeopardize the study. The LOAEL was based on testicular degeneration (hypospermia, interstitial cell hyperplasia of Leydig cells, and germinal cell degeneration) in males, and combined lung adenomas and carcinomas in females. Findings of hyperplasia and neoplasia in the lungs of males were not considered toxicologically significant because they were seen at doses above the MTD. Findings in females of statistically significant increases in lung adenomas and combined lung adenomas/carcinomas were, however, considered toxicologically significant.

The Agency's Cancer Peer Review Committee classified hydramethylnon as a Group C-possible human carcinogen, and recommended that, for the purpose of risk characterization, the Reference Dose approach should be used for quantification of human risk. This classification was based upon statistically significant increases in lung adenomas and combined lung adenomas/carcinomas in female mice. Dietary risk concerns due to long-term consumption of hydramethylnon residues are adequately addressed by the chronic exposure analysis using the RfD.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(F) of the FFDCA 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: Condition 1, 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; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, 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 PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

A routine chronic dietary exposure analysis for pineapple was based on 100% of pineapple crop treated, and 100% of grasses, forage (pasture and rangeland) treated with hydramethylnon.

The Agency believes that the three conditions previously discussed have been met. With respect to Condition 1, EPA used a conservative, model assessment as outlined in Unit III.C.1.ii. above, using tolerance-level residues and 100% CT for the proposed commodity pineapple, and existing commodities. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which hydramethylnon may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for hydramethylnon in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the use pattern, physical characteristics and environmental fate of hydramethylnon.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The screening concentation in ground water (SCI-GROW) model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1

model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides and an index reservoir with the percent crop area adjustment.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal and transformation of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide an initial screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations EECs from these models to quantify drinking water exposure and risk as a percent of reference dose or percent of population adusted dose (%RfD or %PAD). Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to hydramethylnon they are further discussed in the aggregate risk sections in Unit III.E.

Based on the FIRST and SCI-GROW models the EECs of hydramethylnon for acute exposures are estimated to be 76.09 parts per billion (ppb) for surface water and 0.035 ppb for ground water. The EECs for chronic exposures are estimated to be 1.45 ppb for surface water and 0.035 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Hydramethylnon is currently registered for use on the following residential non-dietary sites: Hydramethylnon is used as a bait in child resistant packaging (CRP) and as a gel bait to control ants and roaches indoors, and as a granular formulation to control ants in yards and on lawns. It is also applied by pest control operators (PCOs) in the same forms for indoor and outdoor pest control. The risk assessment was conducted using the following residential exposure assumptions: The Agency has completed a non-dietary exposure and risk assessment for hydramethylnon including the following uses: residential consumers applying granular and gel formulations; children and adults contacting recreational turf or residential lawns treated with hydramethylnon; and toddlers' incidental nondietary ingestion of products applied around the home. Non-occupational handler exposures from the granular formulations applied to outdoor residential sites are assumed to be short-term in duration, based on rapid dissipation and insect foraging.

No chemical-specific data were submitted for the registration of hydramethylnon uses. Per an Agency policy, non-occupational handler assessments are based on surrogate unit exposures from the draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments (12/18/97) and recommended approaches by the Agency's Exposure Science Advisory Committee (ExpoSAC). Updates to the Residential SOPs (02/01) alter the residential postapplication scenario assumptions. These updated assumptions are expected to better represent residential exposure and are still considered to be high-end, screening level assumptions. The non-occupational handler assessments for push type granular spreaders were based on surrogate unit exposures from two Outdoor Residential Exposure Task Force (ORETF) studies.

The ant bait stations containing hydramethylnon are in child-resistant packaging (CRP). The bait stations are supposed to be placed in less accessible locations such as in or under kitchen counters. However, handling or mouthing of the bait stations is the most commonly reported incidental ''exposure'' to hydramethylnon. Such exposures involve, at most, children mouthing the bait container with little or no contact with the actual bait. In the absence of an applicable acute dietary endpoint, and with the vast majority of incident data resulting in little or no health effects, no quantitative assessment of accidental exposure to the internal contents of bait stations was conducted. The gel product containing hydramethylnon is supposed to be applied in dime-sized portions in locations inaccessible to children. Accidental ingestion of gel from such application is considered unlikely and was therefore not assessed.

Adult consumer exposures when installing and removing bait stations are expected to be minimal. Consumer exposure when applying the gel compound from a syringe is considered negligible. Limited accessibility (i.e., crack, crevice, behind appliances, in crawl spaces) of the gel and granular formulations when used by professional applicators in the home make it unlikely that residents would be exposed to these formulations indoors. For the proposed application of granules to outdoor residential sites, dermal MOEs calculated for non-occupational handlers were 10,000 or greater.

Dermal postapplication exposure from lawns treated with hydramethylnon granules at the maximum application rate of 2.2 lb product per acre (0.022 lb ai/A) were estimated using standard assumptions, as no chemical-specific residue data were available. For adults and children playing actively for two hours on a just-treated lawn, the estimated MOEs were 41,000 and 24,000, respectively. The aggregate (dermal, hand-mouth and object-mouth) MOE for a 15 kg child playing on a lawn was 4,000. The MOE for incidental ingestion of 3 mg of 1% hydramethylnon granules found on the surface of the lawn was 850. The hydramethylnon granules are formulated as small granules to allow for ant removal, and are therefore not easily noticed by a child, and ingestion is unlikely.

4. *Cumulative exposure to 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.''

EPA does not have, at this time, available data to determine whether hydramethylnon 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, hydramethylnon 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 hydramethylnon 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. 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.* The Agency has concluded that there is no concern for pre- and/or postnatal toxicity resulting from exposure to hydramethylnon.

3. *Conclusion.* There is a complete toxicity data base for hydramethylnon and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency determined that no special FQPA Safety Factor is needed (1x) for hydramethylnon. The exposure databases (dietary food, drinking water, and residential) are complete and the risk assessment for each potential exposure scenario includes all metabolites and/or degradates of concern and does not underestimate the potential risk for infants and children.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to hydramethylnon will occupy <1% of the aPAD for females 13 years and older. In addition, there is potential for acute dietary exposure to hydramethylnon in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO HYDRAMETHYLNON.

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females (13–49 years old)	0.05	<1	76.09	0.035	1,500

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to hydramethylnon from food will utilize <1% of the cPAD for the U.S. population, and <1% (0.02%) of the cPAD for children 1–2 years old. Based on the use pattern, chronic residential exposure to residues of hydramethylnon is not expected. In addition, there is potential for chronic dietary exposure to hydramethylnon in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO HYDRAMETHYLNON

Population Subgroup	cPAD mg/kg/day	Chronic Food Exposure (mg/kg/day)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.017	0.000005	1.45	0.035	600
All infants (<1 year old)	0.017	0.000012	1.45	0.035	170
Children (1–2 years old)	0.017	0.000026	1.45	0.035	170
Children (3–5 years old)	0.017	0.000016	1.45	0.035	170

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO HYDRAMETHYLNON—Continued

Population Subgroup	cPAD mg/kg/day	Chronic Food Exposure (mg/kg/day)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
Children (6–12 years old)	0.017	0.000008	1.45	0.035	170
Youth (13–19 years old)	0.017	0.000002	1.45	0.035	170
Adults (20–49 years old)	0.017	0.000003	1.45	0.035	600
Females (13–49 years old)	0.017	0.000004	1.45	0.035	510
Adults (50+ years old)	0.017	0.000002	1.45	0.035	600

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Hydramethylnon is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for hydramethylnon.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of exposures for both adults (MOE = 8,000; handler and post-application) and children (MOE = 680; post-application). Therefore, the turf-treatment exposure estimates were aggregated with the chronic dietary (food) to provide a worst-case estimate of short-term aggregate risk for the U.S. population and children 1–2 years old (the child population subgroup with the highest estimated average (chronic) dietary food exposure). These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of hydramethylnon in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 5:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO HYDRAMETHYLNON

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
US Population	7,700	100	76.09	0.035	580
Children 1–2 years old	3,300	100	76.09	0.035	165

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Though residential exposure could occur with the use of hydramethylnon, an intermediate-term aggregate risk assessment was not performed because it is based on the same toxic endpoint and dose as the short-term, and the higher exposure used in the short-term assessment represents a worse case.

5. *Aggregate cancer risk for U.S. population*. A separate cancer aggregate risk assessment was not performed because the Reference Dose approach was recommended for quantification of human risk. Cancer risks are adequately addressed by the chronic aggregate and assessment which used the chronic reference dose (cRfD).

6. *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 hydramethylnon residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The method presented by BASF Corporation and designated M 2458, is the predecessor to method M 2458.01 for which BASF Corporation has submitted as an independent method validation. The updated method corrects some typographical errors and clarifies some of the fractionation steps. Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. 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*.

B. International Residue Limits

No maximum residue limits for hydramethylnon in/on pineapple have been established or proposed by Codex, Canada, or Mexico for any agricultural commodity; therefore, no compatibility concerns exist with respect to U.S. tolerances.

C. Conditions

The following studies are required to further characterize the environmental effects of hydramethylnon: Estuarine/marine fish LC_{50} (72–1), Estuarine/marine invertebrate EC_{50} (72–2), and Sediment Toxicity Testing (Harmonized guidelines 850.1735 and 850.1740). In addition, the following studies are required for any future expansion of hydramethylnon uses: Aquatic Photodegradation (161–2), Aerobic Aquatic Metabolism (162–4), and Terrestrial Field Dissipation (164–1).

D. Recommendation for Tolerances

The residue chemistry and toxicological databases support the requested tolerance of 0.05 ppm for hydramethylnon on pineapple. The Agency has also previously recommended that the grass (pasture and rangeland) tolerance be increased to 2.0 ppm and the grass hay (pasture and rangeland) tolerance be increased to 0.1 ppm (Hydramethylnon RED, EPA 738–R–98–023, 12/98).

V. Conclusion

Therefore, the tolerance is established for residues of hydramethylnon, in or on pineapple at 0.05 ppm., and revised for grass (pasture and rangeland) at 2.0 ppm, and grass hay (pasture and rangeland) at 0.1 ppm respectively.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need To Do To File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0251 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 14, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). 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.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

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 the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0251, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a 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(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this 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 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 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). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, 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. 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 final 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 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 13175, 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 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 rule.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final 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: July 31, 2003.

Debra Edwards,

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), 346(a) and 371.

■ 2. Section 180.395 is amended by adding alphabetically the commodity ''pineapple'' to the table in paragraph (a) to read as follows:

§ 180.395 Hydramethylnon; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Pineapple	0.05
* * * * *	

[FR Doc. 03–20432 Filed 8–12–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0134; FRL–7320–5]

Diallyl Sulfides; Exemption from the Requirement of a Tolerance; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: EPA issued a final rule in the **Federal Register** of July 9, 2003, establishing an exemption from the requirement of a tolerance for residues of diallyl sulfides (DADs) in/or garlic, leeks, onions, and shallots. This document corrects a typographical error in the preamble that appeared in that document.

DATES: This document is effective on August 13, 2003.

FOR FURTHER INFORMATION CONTACT: Driss Benmhend, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9525; e-mail address: *benmhend@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

The Agency included in the final rule a list of those who may be potentially affected by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0134. The official public