nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.355 [Amended]

■ 2. Section 558.355 *Monensin* is amended in paragraph (f)(1)(xiv)*(b)* after ''046573'' by adding ''and 053389''.

Dated: September 11, 2003.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 03–24436 Filed 9–26–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 26, 161, 164, and 165

[USCG–2003–14757]

RIN 1625–AA67

Automatic Identification System; Vessel Carriage Requirement

AGENCY: Coast Guard, DHS.

ACTION: Policy statement.

SUMMARY: The Coast Guard is announcing its policy and intent to establish one uniform compliance date for U.S. domestic vessels subject to Automatic Identification System carriage regulations while transiting a Vessel Traffic Service (VTS) area. On July 1, 2003, the Coast Guard published a temporary interim rule that established 3 different compliance dates, depending on particular VTS areas. This policy statement aligns these dates with the deadline date of the Maritime Transportation Security Act of 2002.

DATES: This policy is effective on September 29, 2003.

FOR FURTHER INFORMATION CONTACT: If you have questions on this Policy Statement, contact Mr. Jorge Arroyo, U.S. Coast Guard Office of Vessel Traffic Management (G–MWV), by telephone 202–267–6277, toll-free telephone 1–800–842–8740 ext. 7–6277, or electronic mail *JArroyo@comdt.uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2003, we published a temporary interim rule with request for comments and notice of public meeting titled ''Automatic Identification System; Vessel Carriage Requirement'' in the **Federal Register** (68 FR 39353). This temporary interim rule was one of a series of temporary interim rules on maritime security published in the July 1, 2003, issue of the **Federal Register**. On July 16, 2003, we published a document correcting typographical errors and omissions in that rule (68 FR 41913). The temporary interim rule established an Automatic Identification System (AIS) compliance date that varies depending upon VTS area. They are as follows:

(1) For VTS St. Marys River, not later than December 31, 2003;

(2) For VTS Berwick Bay, VMRS Los Angeles/Long Beach, VTS Lower Mississippi River, VTS Port Arthur and VTS Prince William Sound, not later than July 1, 2004; and

(3) For VTS Houston-Galveston, VTS New York, VTS Puget Sound, and VTS San Francisco, not later than December 31, 2004.

These deadline dates were established to coincide with anticipated AIS-capability at each of these respective ports via our Ports and Waterways Safety System (PAWSS) upgrades. PAWSS is an effort to establish a national transportation system that collects, processes, and disseminates information on the marine operating environment and maritime vessel traffic in major U.S. ports and waterways. Work continues on schedule in our PAWSS process; however, we recognize that having differing deadline dates has caused unwarranted confusion and may place certain vessels at a disadvantage of reaping market benefits. Therefore, the Coast Guard will amend its temporary interim rule, by a forthcoming final rule, that will adopt December 31, 2004, as the compliance date for all VTS users, not on international voyage, that are subject to the provisions of 33 CFR 164.46(b).

Policy Statement

Until the Coast Guard publishes its final rule regarding AIS carriage requirements, the following policy applies:

The Coast Guard will not enforce the deadline dates as stated in 33 CFR 164.46(c)(1) through (4).

How Long Will This Policy Remain in Effect?

This policy will remain in effect until publication of the final rule regarding AIS carriage [USCG 2003–14757], that we anticipate publishing prior to October 25, 2003. In the final rule we intend to adopt December 31, 2004, as the deadline date for domestic AIS carriage for those vessels denoted in 33 CFR 164.46(b).

Dated: September, 22 2003.

T.H. Gilmour,

Rear Admiral, Coast Guard, Assistant Commandant for Marine Safety, Security and Environmental Protection.

[FR Doc. 03–24571 Filed 9–26–03; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0303; FRL–7327–3]

Dimethomorph; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of dimethomorph in or on brassica, leafy greens, subgroup 5B; taro, corm; taro, leaves; and vegetable, fruiting, group 8. EPA is also deleting certain dimethomorph tolerances that are no longer needed as a result of this action. Interregional Research Project Number 4 (IR-4) requested these tolerances 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 September 29, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0303, must be received on or before November 28, 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: Shaja R. Brothers, Registration Division

(7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. 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–2003–0303. 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.

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 August 20, 2003 (68 FR 50138) (FRL–7321–7), 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 pesticide petitions (PP 2E6483 and 3E6558) by IR-4, 681 US Highway #1 South, New Brunswick, NJ 08902–3390. That notice included a summary of the petitions prepared by BASF Corporation, the registrant.

The petitions requested that 40 CFR 180.493 be amended by establishing tolerances for residues of the fungicide, dimethomorph,(*E,Z*) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]morpholine in or on the following commodities: Brassica, leafy greens, subgroup 5B at 20.0 part per million (ppm); taro, corm at 0.5 ppm; taro, leaves at 6.0 ppm; and vegetable, fruiting, group 8 at 2.0 ppm. The tolerance petition for vegetable, fruiting, group 8 was subsequently amended to propose the tolerance at 1.5 ppm. EPA is also deleting tolerances for tomato, fruit at 0.5 ppm, and tomato, paste at 1.0 ppm established under section 180.493 (a). These commodities will be covered by the tolerance for vegetable, fruiting, group 8 at 1.5 ppm. There were no comments received on these petitions.

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 rasonable 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 tolerances for residues of dimethomorph on brassica, leafy greens, subgroup 5B at 20.0 ppm; taro, corm at 0.5 ppm; taro, leaves at 6.0 ppm; and vegetable, fruiting, group 8 at 1.5 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follow.

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 dimethomorph are discussed in the **Federal Register** of September 27, 2002 (67 FR 60916) (FRL–7199–2).

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 intraspecies 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 dimethomorph used for human risk assessment is shown is shown in Table 1 of this unit:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DIMETHOMORPH FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Endpoint for Risk Assessment	Study and Toxicological Effects
Acute dietary females 13-50 years of age	Not applicable	Not applicable	No endpoint attributable to a single dose was identified.
Acute dietary general population including infants and children	Not applicable	Not applicable	No endpoint attributable to a single dose was identified
Chronic dietary all populations	NOAEL= 11 mg/kg/day UF = 100 Chronic RfD = 0.1 mg/kg/day	Special FQPA SF = 1 cPAD = chronic RfD/Special FQPA SF = 0.1 mg/kg/day	Carcinogenicity study in the rat LOAEL = 46.3 mg/kg/day based on decreased body weight and statistically significant increases in liver lesions in female rats
Short-term dermal (1 to 7 days)	Oral study NOAEL= 60 mg/kg/day (dermal absorption factor = 5 %)	LOC for MOE = 100	Developmental toxicity study in the rat LOAEL = 160 mg/kg/day based on decreased body weight, decreased body weight gain, and decreased food consumption
Intermediate-term dermal (1 week to several months)	Oral study NOAEL= 15 mg/kg/day (dermal absorption factor = 5 %	LOC for MOE = 100	Subchronic feeding study in dogs LOAEL = 43 mg/kg/day based on decreased absolute and relative prostate weight and possible threshold liver effects
Long-term dermal (several months to lifetime)	Not applicable	Not applicable	The current use pattern does not indicate a concern for long-term exposure/risk
Short-term inhalation (1 to 7 days)	Oral study NOAEL= 60 mg/kg/day (inhalation absorption factor = 100 %)	LOC for MOE = 100	Developmental toxicity study in the rat LOAEL = 160 mg/kg/day based on decreased body weight, decreased body weight gain, and decreased food consumption
Intermediate-term nhalation (1 week to several months)	Oral study NOAEL= 15 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100	Subchronic feeding study in dogs LOAEL = 43 mg/kg/day based on decreased absolute and relative prostate weight and possible threshold liver effects
Long-term inhalation (several months to lifetime)	Not applicable	Not applicable	The current use pattern does not indicate a concern for long-term exposure/risk

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR DIMETHOMORPH FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Endpoint for Risk Assessment	Study and Toxicological Effects
Cancer (oral, dermal, inhalation)	Not applicable	Not applicable	This chemical is classified as ''not likely'' to be a human carcinogen

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Tolerances have been established (40 CFR 180.493) for the residues of dimethomorph, in or on [grape; grape, raisin; hop, dried cones; lettuce, head; lettuce, leaf; potato, wet peel; tomato; tomato, paste; vegetable, bulb, group 3; and vegetable, cucurbit, group 9. Time-limited tolerances are also established for residues of dimethomorph in connection with use of the pesticide under emergency exemptions pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act for cantaloupe, cucumber, squash, and watermelon at 1.0 ppm set to expire on December 31, 2003. Additionally, time-limited tolerances are established for inadvertent or indirect residues of dimethomorph in or on the following raw agricultural commodities when present therein as a result of the application of dimethomorph to growing crops: grain, cereal group, fodder; grain, cereal group, forage; grain, cereal group, grain; grain, cereal group, hay; and grain, cereal group, straw at 0.15 ppm, set to expire on May 12, 2004. Risk assessments were conducted by EPA to assess dietary exposures from dimethomorph in food as follows:

i. *Acute exposure*. A quantitative acute dietary exposure and risk assessment was not conducted for dimethomorph since an acute oral endpoint attributed to a single-dose exposure could not be identified in any of the toxicology studies, including developmental and maternal toxicity in the developmental toxicity studies. No acute risk is expected from exposure to dimethomorph.

ii. *Chronic exposure*. In conducting this acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM™/FCID) which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions was made for the chronic exposure assessment: The chronic dietary risk assessment for dimethomorph assumed tolerance level residues and 100% crop treated (Tier 1) for all registered and proposed crops.

iii. *Cancer*. EPA has classified dimethomorph as a ''not likely'' human carcinogen. Therefore, a quantitative cancer dietary exposure and risk assessment was not performed.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for dimethomorph 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 physical characteristics of dimethomorph.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and Screening Concentrations in Ground Water (SCI-GROW), which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a Tier 1 model) before using PRZM/EXAMS (a Tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

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 of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse 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 %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. ince DWLOCs address total aggregate exposure to dimethomorph they are further discussed in the aggregate risk sections in Unit E.

Based on the GENEEC and SCI-GROW models the EECs of dimethomorph for acute exposures are estimated to be 79.8 parts per billion (ppb) for surface water and 0.30 ppb for ground water. The EECs for chronic exposures are estimated to be 28.5 ppb for surface water and 0.30 ppb for ground water.

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 of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a screen for sorting out pesticides for which it is unlikely that drinking water concentrations would 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 EECs from these models to quantify drinking water exposure and risk as a %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

dimethomorph they are further discussed in the aggregate risk Unit E.

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).

Dimethomorph is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider *available information* concerning the cumulative effects of a particular pesticide's residues and *other substances that have a common mechanism of toxicity.*

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

D. Safety Factor for Infants and Children

1.*In general*. Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. The developmental and reproductive toxicity data did not indicate increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.

3. *Conclusion*. There is a complete toxicity data base for dimethomorph and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be reduced to 1X. The FQPA SF is removed because: Acceptable developmental toxicity studies in the rat and the rabbit are available, as is an acceptable 2–generation reproduction study in the rat and there is no indication of qualitative or quantitative increased susceptibility of rats and rabbits to in utero or postnatal exposure. A developmental neurotoxicity study is not required for dimethomorph. The dietary (food and water) exposure assessments are not expected to underestimate the potential exposures for infants and children from the use of dimethomorph. Residential exposure to dimethomorph is not expected since there are no registered residential uses for the pesticide.

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, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to dimethomorph from food will utilize 7% of the cPAD for the U.S. population, 0.8% of the cPAD for all infants < 1 year old, 16% of the cPAD for children 1–2 years old (the most highly exposed population subgroup), and 6% of the cPAD for females 13-49 years old. Based on the lack of residential uses, chronic residential exposure to residues of dimethomorph is not expected. In addition, there is potential for chronic dietary exposure to dimethomorph 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 Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO DIMETHOMORPH

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.10	7	28.50	0.30	3,253
All infants (<1 year old)	0.10	0.8	28.50	0.30	960
Children (1-2 years old)	0.10	16	28.50	0.30	842
Females (13-49 years old)	0.10	6	28.50	0.30	2,812

2. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Dimethomorph is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

3. *Aggregate cancer risk for U.S. population*. Dimethomorph is no carcinogenic. This classification was based upon lack of evidence of carcinogenicity in rats and mice. The Agency concludes that the pesticidal uses of dimethomorph are not likely to pose a cancer risk to humans.

4. *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 dimethomorph residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

A reliable method for the determination of dimethomorph residues in fruiting vegetables crop group 8, leafy brassica greens subgroup 5B, taro leaves and roots exists; this method is the FDA Multi-Residue Method, Protocol D, as published in the Pesticide Analytical Manual I.

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

There are no established or proposed Codex, Canadian or Mexican maximum residue limits or tolerances for dimethomorph in or on taro, corm; taro, leaves; brassica, leafy greens, subgroup 5B; or vegetable, fruiting, group 8.

V. Conclusion

Therefore, the tolerances are established for residues of dimethomorph, in or on brassica, leafy greens, subgroup 5B; taro, corm; taro, leaves; and vegetable, fruiting, group 8.

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 o ''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–2003–0303 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 November 28, 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–2003–0303, 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 tolerances 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 tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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:September 22, 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 180.493 is amended by removing the entries ''tomato'' and ''tomato, paste'' and by alphabetically adding the following commodities to the table in paragraph (a) to read follows:

§ 180.493 Dimethomorph; tolerances for residues.

(a) * * *

Commodity	Parts per million
Brassica, leafy greens, subgroup 5B	20.0
* * * * *	
Taro, corm	0.5
Taro, leaves	6.0
* * * * *	
Vegetable, fruiting, group 8	1.5

* * * * * *

[FR Doc. 03–24564 Filed 9–26–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0058; FRL–7327–9]

Glufosinate Ammonium; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of glufosinate ammonium and its metabolites in or on certain raw agricultural commodities. Aventis CropScience USA, now Bayer CropScience, and Interregional Research Project Number 4 (IR-4) requested these tolerances 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 September 29, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0058, must be received on or before November 28, 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: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: 703–305–6224; e-mail address: *miller.joanne@epamail.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 categories and entities may include, but are not limited to:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. 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–2003–0058. 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 May 19, 2000 (65 FR 31904) (FRL–6558–2), 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 0F6140) by Aventis CropScience USA, now Bayer CropScience, PO Box 12014, 2 T. W. Alexander Drive, Research Triangle Park, NC 27709. That notice included a summary of the petition prepared by Bayer CropScience, the registrant. There were no comments received in response to the notice of filing.

In the **Federal Register** of July 24, 2002 (67 FR 48465) (FRL–7184–6), 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 OF6210) by Aventis CropScience USA, now Bayer CropScience, PO Box 12014, 2 T. W. Alexander Drive, Research Triangle Park, NC 27709. That notice included a summary of the petition prepared by Bayer CropScience, the registrant. Comments on the petition were filed by Neil J. Carman, Ph.D. of the Sierra Club