

telephone number: (410) 305-2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

#### B. International Residue Limits

There are no Codex, Canadian, or Mexican Maximum Residue Limits (MRLs) for difenoconazole.

#### VI. Conclusion

Therefore, time-limited tolerances are established for residues of difenoconazole, 1-[2-[2-chloro-4-(4-chlorophenoxy) phenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole, in or on almond at 0.05 parts per million (ppm), almond, hulls at 5.0 (ppm), and cantaloupe at 1.0 (ppm), cucumber at 1.0 (ppm), and watermelon at 1.0 (ppm). These tolerances expire and are revoked on December 31, 2011.

#### VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under sections 408(e) and 408(l)(6) of 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 final rule has been exempted from review under Executive Order 12866, this final 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

Since tolerances and exemptions that are established in accordance with sections 408(e) and 408(l)(6) of 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions

of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

#### VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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 25, 2008.

**Lois Rossi,**

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

■ Therefore, 40 CFR chapter I is amended as follows:

#### PART 180—[AMENDED]

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

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

■ 2. Section 180.475 is amended by adding text to paragraph (b) to read as follows:

#### § 180.475 Difenoconazole; tolerances for residues.

\* \* \* \* \*

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of the fungicide difenoconazole in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the table.

Commodity	Parts per million	Expiration/revocation date
Almond .....	0.05	12/31/11
Almond, hulls ....	5.0	12/31/11
Cantaloupe .....	1.0	12/31/11
Cucumber .....	1.0	12/31/11
Watermelon .....	1.0	12/31/11

\* \* \* \* \*

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA-HQ-OPP-2007-0221; FRL-8367-5]

#### Dodine; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of dodine in or on bananas and peanuts. Agriphar S.A. c/o Ceres International LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective August 6, 2008. Objections and requests for hearings must be received on or before October 6, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0221. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or

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

**FOR FURTHER INFORMATION CONTACT:**

Mary L. Waller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9354 e-mail address: [waller.mary@epa.gov](mailto:waller.mary@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 those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide 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 Access Electronic Copies of this Document?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Printing Office’s pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2007-0221 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 as required by 40 CFR part 178 on or before October 6, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2007-0221, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket’s normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

**II. Petition for Tolerance**

In the **Federal Register** of May 9, 2007 (72 FR 26372) (FRL-8121-5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F7185) by Agriphar S.A. c/o Ceres International LLC, 1087 Heartsease Dr., West Chester, PA 10382. The petition requested that 40 CFR 180.172 be amended by establishing tolerances for residues of the fungicide dodine, n-dodecylguanidine acetate, in or on bananas at 0.50 parts per million (ppm) and on peanuts at 0.03 ppm. That notice referenced a summary of the petition prepared by Agriphar S.A. c/o Ceres International LLC, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA’s response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has lowered the tolerance for peanuts from 0.03 ppm to 0.013 ppm. The reason for this change is explained in Unit IV.D.

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

Section 408(b)(2)(A)(i) of 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 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 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. . . .”

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of 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 for the petitioned-for tolerances for residues of dodine on bananas at 0.50 ppm and on peanuts at

0.013 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

#### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Technical dodine has moderate toxicity via the acute oral, dermal and inhalation routes of exposure. It is a severe eye irritant and causes severe dermal irritation; it is not a skin sensitizer. A definitive target organ has not been identified for dodine. The most common effects observed in subchronic and chronic oral and inhalation studies were decreases in food consumption, body weight and/or body weight gain. There is no evidence of neurotoxicity. Effects from dermal exposure were limited to dermal lesions. There is no evidence of increased susceptibility (quantitative or qualitative) in pups versus adults based on rat and rabbit developmental studies and the rat multi-generation reproduction study. A weight of evidence evaluation of the carcinogenic potential of dodine was performed, and based on the results it was concluded that there is no evidence of carcinogenicity after exposure to dodine. All toxicological endpoints chosen for risk assessment were based on body weight effects plus, in the case of inhalation, reduced food consumption.

Specific information on the studies received and the nature of the adverse effects caused by dodine as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document *Dodine: Human Health Risk Assessment for Proposed Use Bananas and Peanuts*, pages 12 and 44 in docket ID number EPA-HQ-OPP-2007-0221.

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be

determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account 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. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for dodine used for human risk assessment can be found at <http://www.regulations.gov> in document *Dodine: Human Health Risk Assessment for Proposed Use Bananas and Peanuts*, page 17 in docket ID number EPA-HQ-OPP-2007-0221.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to dodine, EPA considered exposure under the petitioned-for tolerances as well as all existing dodine tolerances in (40 CFR 180.172). EPA assessed dietary exposures from dodine in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for dodine; therefore, a quantitative acute dietary exposure assessment is unnecessary

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 (CSFII). As to residue levels in food, EPA assumed that tolerance level residues were used for all crops. In terms of extent of usage, percent crop treated information was used for pome fruit, stone fruit, strawberry, pecan and walnut. One hundred percent crop treated was assumed for banana and peanut crops.

iii. *Cancer.* There was equivocal evidence of carcinogenicity in a mouse carcinogenicity study. However, based on a weight of evidence evaluation of the carcinogenic potential of dodine, the Agency concluded that there is no evidence of carcinogenicity after exposure to dodine. Factors bearing on this weight of the evidence determination are described in *Dodine: Human Health Risk Assessment for Proposed Use Bananas and Peanuts*, pages 20-21 in docket ID number EPA-HQ-OPP-2007-0221. EPA principally relied on the fact that the only evidence of cancer was a finding of statistically significant liver tumors (primarily adenomas) in female mice at the highest dose tested and no evidence of genotoxicity was found. There was no evidence of cancer in male mice or rats.

iv. *Percent crop treated (PCT) information.* Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- *Condition a:* 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 the pesticide residue.

- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.

- *Condition c:* 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 FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

The Agency used the following PCT information for the currently registered uses of dodine: 10% PCT for pears and quinces; 5% PCT for apples, crabapples, loquats, cherries, walnuts and pecans; and 1% PCT for strawberries, apricots, nectarines, peaches, and plums.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which dodine may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for dodine in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of dodine. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at

<http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST), and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of dodine for chronic exposures for non-cancer assessments are estimated to be 4.0 parts per billion (ppb) for surface water and <0.08 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 4.0 ppb was used to assess the contribution to drinking 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).

Dodine is not registered for any specific use patterns that would result in residential exposure. However, a closely related chemical, dodecylguanidine hydrochloride (DGH) is used as an antimicrobial in household, industrial, and commercial products having residential and non-occupational exposure potential. DGH is used as a bacteriostat in paints and in absorbent material in disposal diapers. Dodine and DGH have similar chemical compositions and properties and are therefore considered bio-equivalents.

Residential painters may have short-term dermal and inhalation exposure as a result of using DGH treated paint. Infants < 1-year old may have short-, intermediate, and long term dermal exposure as a result of wearing DGH impregnated diapers. Inhalation exposure of infants and children is expected to be negligible. Although small children may have short-term post application oral exposure as a result of accidental ingestion of paint chips which contain DGH, the Agency does not believe that this would occur on a regular basis.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of 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 has not found dodine to share a common mechanism of toxicity with any other substances, and dodine does not appear to produce a toxic metabolite

produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that dodine does not have 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 EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence (quantitative or qualitative) of increased susceptibility and no residual uncertainties with regard to prenatal and/or postnatal toxicity following *in utero* exposure to rats or rabbits and prenatal and/or postnatal exposure to rats. In a rat developmental toxicity study, decreased body weight gain and food consumption were observed at  $\geq 45$  milligrams/kilograms/day (mg/kg/day) in maternal animals. No treatment-related effects were observed in fetuses up to 90 mg/kg/day. In a rabbit developmental toxicity study, dams demonstrated decreased food consumption at 80 mg/kg/day; however, this finding was not considered adverse. No treatment-related effects were observed in fetuses up to 80 mg/kg/day. In a 2-generation reproduction toxicity study in rats, decreases in parental body weight, body weight gain and food consumption were noted in both generations of rats at 53 mg/kg/day. Additionally at 53 mg/kg/day, the offspring of both generations demonstrated decreased body weight after postnatal day 4 which continued through pre-mating.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for dodine is complete.

ii. EPA concluded that dodine is not a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. Possible neurological clinical signs (excessive salivation and hunched posture/hypoactivity) were observed in chronic studies in rats and mice but were not dose-related or statistically significant. Excessive salivation in the chronic study in dogs showed a treatment related dose response. However, the effect was not consistent with a neurological adverse effect since it was seen prior to dosing and was a persistent finding throughout the study. In addition, no evidence of neuropathology was observed in the available studies. Therefore, it was determined that there was no evidence of neurotoxicity. Based on the weight of evidence, the Agency determined that a developmental neurotoxicity study is not required.

iii. There is no evidence that dodine results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on Agency recommended tolerance-level residues and health-protective modeling assumptions. Although PCT estimates were used for crops with existing tolerances, the use of tolerance values for residue levels will likely overestimate actual exposures. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to dodine in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by dodine.

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

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the

estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. No adverse effect resulting from a single-oral exposure was identified and no acute dietary endpoint was selected. Therefore, dodine is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to dodine from food and water will utilize 20% of the cPAD for (children 1-2 years of age) the population group receiving the greatest exposure. Although dodine is not currently registered for any use patterns that would result in residential exposure, DGH is currently registered for uses that could result in long-term residential post-application exposure and the Agency has determined that it is appropriate to aggregate chronic exposure to dodine through food and water with long-term residential post-application exposure to DGH. EPA has concluded that the combined long-term food, water, and dermal exposure for infants wearing diapers containing DGH treated material results in aggregate MOEs as follows: 300 when using a 5% transfer factor and 100 when using a 30% transfer factor. The Agency believes that a transfer factor of 30% is an overestimate of exposure in determining the amount of DGH transferred to infants from diapers based on a transfer study using dodine-treated paper exposed to extreme conditions. Additionally, the Agency has requested an impregnated diaper migration study as confirmatory data.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Although dodine is not registered for any use patterns that would result in residential exposure, DGH is currently registered for uses that could result in short- and intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure to dodine through food and water with short- and intermediate-term residential exposures to DGH.

Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has

concluded the short- and intermediate-term combined food, water, and residential exposures aggregated result in aggregate MOEs of 4,500 for adult males handling paint and 4,600 for adult females handling paint do not exceed the Agency's level of concern. EPA has concluded that the combined intermediate-term food, water, and dermal exposure for infants wearing diapers containing DGH treated material results in aggregate MOEs of 640 when using a 5% transfer factor and 120 when using a 30% transfer factor. For the reasons stated in Unit III.E.2. the Agency believes the risks do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population.* Based on its weight of the evidence calculation, the Agency believes that there is no cancer risk associated with the use of dodine.

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

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

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

Adequate enforcement methodology (liquid chromatography/mass spectrometry/mass spectrometry) 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](mailto:residuemethods@epa.gov).

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

There are no Codex, Canadian, or Mexican maximum residue limits for dodine on bananas or peanuts.

##### *C. Response to Comments*

There was one favorable comment from Del Monte in favor of establishing the tolerance for use of dodine on bananas in order to control black sigatoka disease.

##### *D. Revisions to Petitioned-For Tolerances*

The proposed tolerance of 0.03 ppm for residues of dodine on peanuts was revised to 0.013 ppm because the tolerances were proposed in terms of dodine free base, and the Agency recalculated the residue results in terms of dodine using a molecular weight conversion factor of 1.258.

**V. Conclusion**

Therefore, tolerances are established for residues of dodine, n-dodecylguanidine acetate, in or on bananas at 0.50 ppm and on peanuts at 0.013 ppm.

**VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances under section 408(d) of 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 final rule has been exempted from review under Executive Order 12866, this final 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such,

the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

**VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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 25, 2008.

**Lois Rossi,**

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

■ Therefore, 40 CFR chapter I is amended as follows:

**PART 180—AMENDED**

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

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

■ 2. Section 180.172 is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

**§ 180.172 Dodine; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * * * *	*
Banana .....	0.50
* * * * *	*
Peanut .....	0.013
* * * * *	*

\* \* \* \* \*

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