Commodity	Parts per million	Expiration/ Revocation Date
* * *	*	*
Mango	0.3	None
Millet, pearl, grain	1.0	None
* * *	*	*
Millet, proso, grain	1.0	None
Oat, grain	0.02	None
Papaya	0.3	None
Passionfruit	0.3	None
Pistachio	0.02	None
* * *	*	*
Pulasan	0.3	None
* * *	*	*
Rambutan	0.3	None
Rye, grain	0.02	None
Sapodilla	0.3	None
Sapote, black	0.3	None
Sapote, mamey	0.3	None
Sapote, white	0.3	None
* * *	*	*
Soursop	0.3	None
Spanish lime	0.3	None
* * *	*	*
Star apple	0.3	None
Starfruit	0.3	None
* * *	*	*
Sugar apple	0.3	None
* * *	*	*
Teosinte, grain	0.3	None
Ti, leaves	10.0	None
* * *	*	*
Turnip greens	10.0	None
* * *	*	*
Watercress	8.0	None
Wax jambu	0.3	None
* * *	*	*

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300964; FRL–6486–2]

RIN 2070–AB78

N,N-diethyl-2-(4-methylbenzyloxy)ethylamine hydrochloride; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for the plant growth regulator *N,N*-diethyl-2-(4-methylbenzyloxy)ethylamine hydrochloride (PT807-HCl), in or on oranges. GMJA Specialties requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective January 12, 2000. Objections and requests for hearings, identified by docket control number OPP–300964, must be received by EPA on or before March 13, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300964 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: 703–305–7740; and e-mail address: giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**--Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–300964. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of November 10, 1999 (64 FR 61336) (FRL–6388–3), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP) for a tolerance by GMJA Specialties. This notice included a summary of the petition prepared by GMJA Specialties, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a tolerance for the plant growth regulator *N,N*-diethyl-2-(4-methylbenzyloxy)ethylamine hydrochloride, in or on oranges at 0.01 (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) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

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

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of *N,N*-diethyl-2-(4-methylbenzyloxy)ethylamine hydrochloride on oranges at 0.01 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows. The term PT807–HCl is equivalent to *N,N*-diethyl 2-(4-methylbenzyloxy)ethylamine hydrochloride.

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 PT807–HCl are discussed in this unit.

The data base adequately characterizes PT807–HCl as having low acute oral, dermal and inhalation toxicity. It is Toxicity Category IV for acute dermal toxicity, acute inhalation toxicity, and primary dermal irritation; Toxicity Category III for acute oral and primary eye irritation; and it is not a dermal sensitizer.

1. *Subchronic mouse feeding study*. A subchronic mouse feeding study with a No Observed Adverse Effect Level (NOAEL) = 7,000 ppm (1,004/1,272 miligrams/kilograms/day (mg/kg/day), in male and females respectively; limit dose). Due to faulty dose concentration analyses, the regulatory usefulness of the NOAEL is in doubt.

2. *Subchronic gavage rat study*. A subchronic gavage rat study with a NOAEL = 30 mg/kg/day and a Lowest Observed Adverse Effect Level (LOAEL) = 300 mg/kg/day based on increased mortality; hyperactivity, hyper-reflexivity, lack of coordination, tremors, convulsions, and increased salivation in males and females, and elevated urinary protein in males.

3. *Subchronic feeding dog study*. A subchronic feeding dog study with a NOAEL = 2,500 ppm (equivalent to 71/78 mg/kg/day) males and females respectively and LOAEL = 7,500 ppm (equivalent to 211/233 mg/kg/day) in males and females respectively, based on pathological changes to the male reproductive organs and possibly the uterus in females.

4. *21 day dermal rat-systemic*. A 21–day dermal rat-systemic. NOAEL greater than 1,000 mg/kg/day (limit dose). Dermal NOAEL = 1,000 mg/kg/day (nonadverse dermal irritation was observed at 1,000 mg/kg/day).

5. *Developmental toxicity rat.*— Maternal NOAEL = 50 mg/kg/day, maternal LOAEL = 250 mg/kg/day, based on clinical signs (post-dosing rooting in the bedding and lethargy) and reduced body weight gains. Developmental NOAEL = 500 mg/kg/day and developmental LOAEL was not observed.

6. *Developmental toxicity rabbit*. Developmental toxicity rabbit-Maternal NOAEL = 10 mg/kg/day, maternal LOAEL = 100 mg/kg/day, based on increased mortality in the mid-and high-dose animals. Developmental NOAEL greater than 200 mg/kg/day and developmental LOAEL was not observed.

7. *Reproductive toxicity rat*. Reproductive toxicity rat-systemic NOAEL = 14.1 mg/kg/day, systemic LOAEL = 114 mg/kg/day based upon decreased body weight and body weight gains. Reproductive NOAEL = 14.1 mg/kg/day for both sexes. Reproductive LOAEL = 114 mg/kg/day for both sexes based on decreased pup body weight and body weight gains, delayed sexual development, reductions in absolute and relative uterus and ovary weights, and histological changes in the uterus, vagina, and ovaries in the females.

8. *Chronic toxicity dog*. Chronic toxicity dog-NOAEL greater than 5,000 ppm. (135.7/151.5 mg/kg/day), males and females. LOAEL was not observed.

9. *18 month carcinogenicity study—mouse*. The NOAEL was 7,000 ppm (1,010/1,250 mg/kg/day), males and females. No LOAEL was observed. Mice were dosed at greater than the limit dose of 1,000 mg/kg/day with no evidence of carcinogenic potential.

10. *Chronic toxicity/Carcinogenicity—rat*. The NOAEL was 500 ppm (20/28 mg/kg/day, males and females. The LOAEL was 5,000 ppm (213/308 mg/kg/day), males and females based on decreased body weight and body weight gains. There was no clear evidence of carcinogenic potential.

11. *Acute neurotoxicity—rats*. The neurotoxicity NOAEL was 50 mg/kg/day and the neurotoxicity LOAEL was 200 mg/kg/day based on slight ataxia in 1 of 11 males. Neurotoxicity at 400 mg/kg included increases in Functional Observation Battery (FOB) clinical signs and decreases in motor activity.

12. *Subchronic neurotoxicity—rats*. Neurotoxicity NOAEL is greater than 5000 ppm. (323/386 mg/kg/day; male and female. Neurotoxicity LOAEL was not observed.

B. Toxicological Endpoints

1. *Acute toxicity*. The acute Reference Dose (RfD) is 0.5 mg/kg/day. The systemic NOAEL of 50 mg/kg/day in the acute neurotoxicity study in rats is based on slight ataxia in males at the LOAEL of 200 mg/kg/day. The FQPA safety factor for protection of infants and children was reduced to 1X. The Acute RfD is identical to the acute population adjusted dose (aPAD). This aPAD applies to all population subgroups.

2. *Short- and intermediate-term toxicity*. There are no registered residential uses of PT807–HCl.

3. *Chronic toxicity*. EPA has established the Chronic RfD at 0.14 mg/kg/day. This RfD is based on the systemic NOAEL of 14.1 mg/kg/day in the reproductive toxicity study in rats, the lowest NOAEL in the most sensitive species. The FQPA safety factor for protection of infants and children was reduced to 1X. The chronic RfD is identical to the chronic population

adjusted dose (cPAD). This cPad applies to all population subgroups.

4. *Carcinogenicity*. This chemical has been classified as a ''not likely human carcinogen.''

C. Exposures and Risks

1. *From food and feed uses.* Tolerances are being established (40 CFR 180.558) for *N,N*-diethyl-2-(4-methylbenzyloxy)ethylamine hydrochloride, at 0.01 ppm, in or on oranges. No other tolerances have been established for this chemical. Risk assessments were conducted by EPA to assess dietary exposures from the use on oranges.

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. For the acute dietary food exposure analyses, tolerance level residues and 100% crop treated (%CT) were used. The Dietary Exposure Evaluation Model (DEEM) acute dietary risk analysis estimates the distribution of single-day exposures for the overall U.S. population and certain subgroups. The analysis evaluates individual food consumption as reported by respondents in the USDA 1989–92 Continuing Survey of Food Intake by Individuals (CSFII) and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of PT807–HCl in the commodity supply.

The acute exposures from food are all less than 1% of the aPAD. This acute risk estimate should be viewed as conservative since these calculated exposures are based on tolerance level residues and 100% CT. Therefore, any additional refinements could reduce estimates significantly.

ii. *Chronic exposure and risk.* The DEEM chronic analysis evaluates food consumption as reported by respondents in the USDA 1989–91 CSFII and accumulates exposure to the chemical for each commodity.

A DEEM chronic exposure analysis was performed using tolerance level residues and 100% CT to estimate the Tier I exposure for the general population and subgroups of interest. Exposures for all population subgroups are less than 1% of the cPAD, and the Agency's level of concern is greater than 100% of cPAD.

2. *From drinking water.* This chemical is very soluble in water and stable in the environment. Based on its chemical properties it is likely that this chemical will move to surface water and groundwater, and it may accumulate in the environment. According to information included in the proposed Ecolyst label, the maximum application rate for this chemical is 0.013 lbs. active ingredient/acre/year. The surface water acute Estimated Environmental Concentrations (EEC) is 4.0 parts per billion (ppb). The surface water chronic EEC is 3.9 ppb. These values represent the 1– in 10–year peak surface concentration and 1– in 10–year mean yearly concentration. The ground water screening concentration, calculated using SCI-GROW is 0.02 ppb. While there may be some potential for PT807–HCl to accumulate in drinking water, EPA believes these values nevertheless represent very conservative exposure estimates because they represent peak concentrations, and because of the conservative nature of the models. Even assuming these conservative estimates, the Agency does not expect the exposures to exceed our level of concern.

The maximum concentrations of PT807–HCl in drinking water is well below the drinking water level of comparison (DWLOC's) and there is reasonable certainty that no harm will result to adults, infants, and children from acute and chronic aggregate exposures.

i *Acute exposure and risk.* The maximum acute EECs of PT807–HCl in surface and groundwater for acute exposure, and the highest value (4.0 ppb) is well below the Agency's calculated DWLOC, which ranged from 5,000 ppb for children (1–6 years) to 18,000 ppb for the U.S. population. The Agency concludes that there is a reasonable certainty that no harm will result to adults, infants and children from acute aggregate exposure to PT807–HCl residues.

ii. *Chronic exposure and risk.* The maximum chronic EECs of PT807–HCl in surface and groundwater for chronic exposure is 3.9 ppb which is very small compared to the DWLOC, which ranged from 1,400 ppb for children (1–6 years) to 4,900 ppb for the U.S. population.

3. *From non-dietary exposure.* Currently, there are no registered uses that could result in residential exposures. Therefore, a residential exposure risk assessment is not required.

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

EPA does not have, at this time, available data to determine whether PT807–HCl 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, PT807–HCl 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 PT807–HCl has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

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

1. *Acute risk.* Acute aggregate risk estimates do not exceed the Agency's level of concern. Using the most conservative Tier I approach, acute dietary risk estimates for PT807–HCl from food for the general U.S. population, infants, and children are less than 1% of the aPAD. The Agency had provided maximum EECs for PT807–HCl in surface and groundwater for acute exposure, and the highest value (4.0 ppb) is well below the Agency's calculated DWLOC, which ranged from 5,000 to 18,000 ppb for various population subgroups. The Agency does not expect the aggregate exposure from water and food to exceed 100% of the aPAD for all U.S. populations.

2. *Chronic risk.* Using the conservative analysis described above, it is estimated that the chronic exposure to PT807–HCl from food for the general U.S. population, infants, and children will utilize less than 1% of the cPAD. Despite the potential for exposure of PT807–HCl in drinking water, the Agency does not expect the aggregate exposure to exceed 100% of the cPAD. The maximum concentration of PT807–HCl in surface and groundwater for chronic exposure is expected to be very small compared to DWLOC.

3. *Short-and intermediate-term risk.* There are no registered residential uses of PT807–HCl. Therefore, no exposure is expected via this route of exposure.

4. *Aggregate cancer risk for U.S. population*. PT807–HCl has been classified by the Agency as a ''not likely human carcinogen'' and is thus not expected to pose a cancer risk to humans.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of PT807–HCl.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*—i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of PT807–HCl, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. In the developmental toxicity study in rats, there was an increased incidence of enlarged ventricles in pups at 500 mg/kg/day. The incidences were within historical limits, however, and occurred at a dose far in excess of the maternal NOAEL of 50 mg/kg/day. No developmental effects were seen in rabbit pups at 200 mg/kg/day, whereas the maternal NOAEL was 10 mg/kg/day.

iii. *Reproductive toxicity study*. In the rat reproductive study, the systemic and reproductive LOAELs were both 114 mg/kg/day at which the parents exhibited decreased body weight and body weight gains, and the pups had decreased body weight and body weight gains, delayed sexual development, reductions in absolute and relative uterus and ovary weights, and histological changes in the uterus, vagina and ovaries in the females.

iv. *Prenatal and postnatal sensitivity*. There is no evidence of increased development or neurological susceptibility in the prenatal pre/postnatal studies.

v. *Conclusion*. There is a complete toxicity data base for PT807– HCl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Therefore, the FQPA safety factor was reduced to 1X for the following reasons:

a. The toxicology database is complete for the assessment of the effects following *in utero* and/or postnatal exposure to PT807–HCl.

b. The toxicity data provided no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.

c. The requirement of a developmental neurotoxicity study is not based on the criteria reflecting some special concern which are generally used for requiring a DNT study and an FQPA safety factor (e.g.: neuropathy in adult animals; CNS malformations following prenatal exposure; brain weight or sexual maturation changes in offspring; and/or functional changes in offspring) and therefore does not warrant an FQPA safety factor.

d. The exposure assessments will not underestimate the potential dietary (food and water) exposures for infants and children from the use of PT807–HCl (currently no residential exposure is expected). Specifically, as to residue in drinking water, EPA took into account that residues may accumulate over time.

2. *Acute risk*. It is estimated that the acute exposure to PT807–HCl from food for infants and children as well as the general U.S. population will utilize less than 1% of the aPAD. EPA generally has no concern for exposures below 100% of the aPAD. Despite the potential for exposure to PT807–HCl in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to PT807–HCl from food will utilize less than 1% of the cPAD for infants and children. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to PT807–HCl in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

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

IV. Other Considerations

A. Metabolism in Plants and Animals

The qualitative nature of the residue in oranges is adequately understood for purpose of this use on oranges. Future uses on crops other than tree fruit will require additional plant metabolism studies. The residue of concern in plants is parent compound only.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (HPLC-uvdetection) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

C. Magnitude of Residues

Based on the available crop field trials, residues in oranges are not expected to exceed 0.01 ppm provided a preharvest interval of 14 days is observed. The submitted orange processing data are adequate. At 5X application rate, residues of PT807–HCl were less than the limit of quantitation (LOQ) (0.01 ppm) in/on whole oranges harvested at 19 days PHI. Residues were below the analytical method's LOQ in orange juice and oil processed from the treated oranges. In dried pulp, residues ranged from 0.015 ppm to 0.017 ppm from the 5X application rate. No tolerances are required for orange processed commodities.

D. International Residue Limits

The Codex Alimentarius Commission, Mexico and Canada have not established maximum residue limits (MRLs) for residues of PT807–HCl in/on plant and animal commodities.

E. Rotational Crop Restrictions

No confined or field rotational crop studies were submitted. The Agency has determined that rotational crop studies are not required for uses of pesticides on oranges as they are not routinely rotated to other crops.

V. Conclusion

Therefore, the tolerance is established for residues of *N,N*-diethyl-2-(4-

methylbenzyloxy)ethylamine hydrochloride on oranges at 0.01 ppm.

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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP–300964 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 March 13, 2000.

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 (1900), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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 (202) 260–4865.

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, 401 M St., SW., Washington, DC 20460.

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, 401 M St., SW., Washington, DC 20460.

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.2. Mail your copies, identified by docket control number OPP–300964, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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 file format 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. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review 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 FFDCA section 408(d), such as the tolerance in this final rule, do not

require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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 FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and 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: December 29, 1999.

Joseph J. Merenda,

Acting Director, 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 180.558 is added to read as follows:

§180.558 N,N-diethyl-2-(4-methylbenzyloxy)ethylamine hydrochloride; tolerances for residues.

(a) *General.* A tolerance for residues of the plant growth regulator *N,N*-diethyl-2-(4-methylenzyloxy)ethylamine hydrochloride in or on raw agricultural commodities is established as follows:

Commodity	Parts per million
Oranges	0.01

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

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

(d) *Indirect or inadvertent residues.* [Reserved]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 257 and 258

[FRL–6521–4]

Adequacy of State Permit Programs Under RCRA Subtitle D

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to streamline the approval process for specific state permit programs for solid waste disposal facilities other than municipal solid waste landfills (MSWLF) that receive conditionally exempt small quantity generator (CESQG) hazardous waste. States whose Subtitle D MSWLF permit programs or Subtitle C hazardous waste management programs have been reviewed and approved or authorized by EPA are eligible for this streamlined approval process if their state programs require the disposal of CESQG hazardous waste in suitable facilities. EPA is issuing an adequacy determination to the state programs for Kansas, Missouri, and Nebraska.

Elsewhere in the proposed rule section of today's **Federal Register**, EPA is proposing the program adequacy of these states and soliciting comment on this decision. If relevant adverse comments are received, EPA will withdraw this direct final rule of program adequacy and address the comments in a subsequent final rule. EPA will not give additional opportunity for comment. If EPA receives relevant adverse comment concerning the adequacy of only certain state programs, the Agency's withdrawal of the direct final rule will only apply to those state programs. Comments on the inclusion or exclusion of one state permit program will not affect the timing of the decision on the other state permit programs.

DATES: This direct final rule is effective on April 11, 2000 unless the Agency receives timely relevant adverse comments by February 11, 2000. Should the Agency receive such relevant adverse comments, EPA will publish a timely withdrawal of this direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Send or hand deliver an original and one copy of your comments referencing docket number R7/ARTD/SWPP-00–01 to: Region VII Information Resource Center, U.S. Environmental Protection Agency, 901 N. 5th Street, Kansas City, Kansas 66101. Comments may also be submitted electronically through the Internet to: r7-library@epa.gov. Comments in electronic format should also be identified by the docket number listed above. All electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

You can view and copy documents pertaining to this regulatory docket in the Region VII Information Resource Center (Library), located on the Plaza Level at the address noted above. The Library is open from 9 a.m. to 3 p.m., Monday through Friday, excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: For general information, call (913) 551–7241 or TTY (913) 321–9516. For information on accessing paper and electronic copies of documents or supporting materials relating to the direct final rule, or for information on specific aspects of this rule, contact Wes Bartley, U.S. EPA Region VII, ARTD/SWPP, 901 N. 5th Street, Kansas City, Kansas 66101,