Al at 2.5 mg/kg/day. This RfD is based on a NOAEL of 250 mg/kg/day from a 2–year feeding study in dogs and the use of a 100 fold safety factor to account for interspecies and intraspecies differences. No appropriate endpoint attributable to a single dose exposure was identified in oral toxicity studies. Therefore, an acute RfD was not established and there is no expectation of acute risk. Since no dermal or systemic toxicity was seen at the limit dose following repeated dermal applications in the 21–day toxicity study using rats, no endpoint value was calculated for short- and intermediate-term exposure and risk. The Agency has concluded that fosetyl-Al is unlikely to pose a carcinogenic hazard to humans. Therefore, a cancer exposure and risk assessment is not appropriate.

i. *Food*. For all currently registered uses of fosetyl-Al, chronic food exposure for various subgroups of the U.S. population was estimated by EPA through the use of the Dietary Exposure Evaluation Model (DEEM) software. The DEEM analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-1991 nationwide Continuing Surveys of Food Intake by Individuals. As the risk estimate was low for even the most highly exposed subpopulation, no anticipated residues were used. One hundred percent crop treated and tolerance level residues were assumed for all crops. Based on the results of this conservative analysis, exposure to fosetyl-Al residues from the proposed uses is expected to be minimal. Aventis Crop Science concludes that dietary exposure to fosetyl-Al resulting from the currently registered and the proposed uses of the product will be well below the Agency's level of concern.

ii. *Drinking water*. There is no established maximum contaminant level or health advisory level for fosetyl-Al. The potential for ground water and/or surface water contamination by fosetyl-Al and its degradates is expected to be very low, in most cases, due to the rapid degradation of the compound in soil to non-toxic degradates under both aerobic and anaerobic conditions. Under aerobic laboratory conditions, the half-life of fosetyl-Al is between 1 and 1.5 hours in loamy sand, silt loam and clay loam and 20 minutes in sandy loam soil. The degradation proceeds through the hydrolysis of the ethyl ester bond, resulting in the formation of phosphorous acid and ethanol. The ethanol is further degraded into carbon dioxide. Based on the short half-life of fosetyl-Al and the known fate of phosphates under anaerobic conditions, EPA determined that an anaerobic soil metabolism study was not necessary. An anaerobic aquatic soil metabolism study was conducted. When anaerobic conditions were established by flooding soil, the half-life was 40 hours with silty clay loam and 14 hours with sandy loam soil. Aventis Crop Science expects that potential fosetyl-Al residues in drinking water are not a significant contribution to aggregate exposure.

2. *Non-dietary exposure*. Fosetyl-Al is currently registered for residential use on turf and ornamental plants. Chronic exposure is not expected for residential uses. There is also no expectation of acute risk. No appropriate endpoint attributable to a single dose exposure was identified in oral toxicity studies and consequently, an acute RfD cannot be calculated. No endpoint value is calculable for short- and intermediate-term exposure and a risk analysis cannot be performed since no dermal or systemic toxicity was seen at the limit dose following repeated dermal applications in the 21–day toxicity study using rats. The Agency has previously concluded that fosetyl-Al is unlikely to pose a carcinogenic hazard to human. Therefore, a cancer exposure and risk assessment is not appropriate. Thus, Aventis Crop Science concludes that the ornamental and turf uses do not add significantly to the aggregate exposure for fosetyl-Al.

D. Cumulative Effects

Effects associated with fosetyl-Al are unlikely to be cumulative with any other compound. The formation of calculi and bladder tumors in rats is the only significant toxicological effect observed with fosetyl-Al. These effects were observed in rat only at a dose which not only exceeds estimated human exposure by several orders of magnitude but is in excess of the EPA dose limit for carcinogenicity studies. Therefore, an aggregate assessment based on common mechanisms of toxicity is not appropriate as exposure to humans will be well below the levels producing calculi and bladder tumors in rats. Further, considering the rapid elimination of fosetyl-Al in the rat metabolism study, any effects associated with fosetyl-Al are unlikely to be cumulative with any other compound. Based on these reasons, only the potential risks of fosetyl-Al are considered in the exposure assessment.

E. Safety Determination

1. *U.S. population*. Chronic risk estimates associated with exposure to fosetyl-Al in food and water are expected to be well below the Agency's level of concern. The DEEM chronic exposure analysis previously performed by the Agency for all currently registered food uses shows that exposure to fosetyl-Al utilizes 3.1% of the cPAD for the U.S. population, 2.7% of the cPAD for females (13–50 years), 6.3% of the cPAD for children 1-6 years old, and 4.2% of the cPAD for non-Hispanic (other than black or white). This analysis was conducted assuming 100% crop treated and tolerance level residue values for all crops. The contribution of fosetyl-Al residues in surface and ground water to chronic aggregate exposure is expected to be minimal. Therefore, Aventis Crop Science concludes that even when considering the potential incremental risk resulting from the proposed uses, there is a reasonable certainty that no harm will result from aggregate exposure to fosetyl-Al residues.

2. *Infants and children*. No indication of increased susceptibility of rat or rabbit fetuses to *in utero* and/or postnatal exposure was noted in the developmental and reproductive toxicity studies. The Agency has previously determined that no additional safety factor to protect infants and children is necessary for this product.

Using the conservative assumptions described in the exposure section, aggregate exposure to fosetyl-Al from currently registered food uses will utilize up to 6.3% of the RfD for infants and children. Even when considering the potential incremental dietary risk resulting from the proposed uses, the potential for exposure to residues in drinking water and from non-dietary, non-occupational exposure, the aggregate exposure to fosetyl-Al is expected to be well below 100% of the RfD. Aventis Crop Science concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to fosetyl-Al residues.

F. International Tolerances

There are presently no Codex Alimentarius Commission maximum residue levels established for residues of fosetyl-Al.

[FR Doc. 01–12906 Filed 5–22–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1023; FRL–6782–5]

Notice of Filing a Pesticide Petition to Establish a Tolerance fora Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–1023, must be received on or before June 22, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1023 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joseph M. Tavano, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8375; e-mail address: tavano.joseph@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 codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing 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 PF–1023. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, 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 Highway, 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.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1023 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–1023. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 11, 2001.

Richard P. Keigwin, Jr., Acting,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Rohm and Haas Company

1F6259

EPA has received a pesticide petition (1F6259) from Rohm and Haas Company, 100 Independence Mall West, Philadelphia, PA 19106–2399 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of methoxyfenozide benzoic acid, 3-methoxy-2-methyl-,2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide in or on the raw agricultural commodity stone fruits crop group and prunes at 5 and 7 parts per million (ppm) respectively. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The qualitative nature of methoxyfenozide residues in plants and animals is adequately understood and was previously published in the **Federal Register** of July 5, 2000 (65 FR 41355) (FRL–6496–5).

2. *Analytical method.* An high performance liquid chromotography using ultra-violet detection (HPLC/UV) method TR 34–00–109 for the enforcement of tolerances in stone fruits has been developed. Confirmatory method validation data have been submitted for this method. The validated limit of quantitation (LOQ) of the analytical method was 0.02 ppm in all matrices for methoxyfenozide.

3. *Magnitude of residues.* Geographically representative field trials with methoxyfenozide 80WP and 2F formulations were conducted to support the proposed crop group tolerance for the stone fruit representative crops peaches, plums and cherries. The results of the field trials indicate that residues of methoxyfenozide will not exceed the proposed crop group tolerance of 5.0 ppm for stone fruits or 7.0 ppm for prunes.

B. Toxicological Profile

The toxicological profile and endpoints for methoxyfenozide which supports this petition to establish tolerances were previously published in the **Federal Register** of July 5, 2000 (65 FR 41355).

B. Aggregate Exposure

1. *Dietary exposure*—i. *Food.* 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. No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicology studies on methoxyfenozide including the acute neurotoxicity study in rats, the developmental toxicity study in rats and the developmental toxicity study in rabbits. Since no acute toxicological endpoints were established, Rohm and Haas considers acute aggregate risk to be negligible.

Rohm and Haas used the Dietary Exposure Evaluation Model™ (DEEM) V.7.075; Novigen Sciences, Washington, DC) software for conducting a chronic dietary (food) risk analysis. DEEM is a dietary exposure analysis system that is used to estimate exposure to a pesticide chemical in foods comprising the diets of the U.S. population, including population subgroups. DEEM contains food consumption data as reported by respondents in the USDA continuing surveys of food intake by individuals conducted in 1994–1996. Rohm and Haas assumed 100% of crops would be treated and contain methoxyfenozide residues at the tolerance level. The following tolerance levels were used in the analysis:

Commodity	Tolerance level, ppm
Bulb vegetables	0.1 ppm
Corn, aspirated grain fractions	1.0 ppm
Corn, field, forage	15 ppm
Corn, field, grain	0.05 ppm
Corn, field, stover (fodder)	105 ppm
Corn, oil	0.2 ppm
Corn, silage	5.0 ppm
Corn, sweet, forage	30 ppm
Corn, sweet (K+CWHR)	0.05 ppm
Corn, sweet, stover (fodder)	60 ppm
Cotton, undelinted seed	2.0 ppm
Fat*	0.5 ppm
Fruiting vegetables	2.0 ppm
Grapes	1.0 ppm
Head and stem brassica (5A)	6.5 ppm
Herbs and spices	8 ppm
Leaf petioles (4B)	10.0 ppm
Leafy brassica greens (5B)	20.0 ppm

Commodity	Tolerance level, ppm
Leafy vegetables (4A)	25 ppm
Leaves of root and tuber vegetables	0.1 ppm
Legume vegetables	0.05 ppm
Liver	0.4 ppm
Meat*	0.02 ppm
Meat byproducts* (except liver)	0.1 ppm
Milk	0.1 ppm
Pome fruit	1.5 ppm
Prunes	7.0 ppm
Raisins	1.5 ppm
Root and tuber vegetables	0.05 ppm
Stone fruits	5.0 ppm

* Of cattle, goats, hogs, horses, and sheep.

Processing factors were also applied to grape juice (1.2x), grape juice concentrate (3.6x), apple juice/cider (1.3x), apple juice concentrate (3.9x), dried apples (8x), dried pears (6.25x), tomato juice (1.5x), tomato puree (3.3x), tomato paste (5.4x), tomato catsup (2.5x), dried tomatoes (14.3x), dehydrated onions (9x), white dry potatoes (6.5x), sprouted soybean seeds (0.33x), corn grain sugar (high fructose corn syrup; 1.5x), dried beef (1.92x), dried veal (1.92x), dried apricots (6.0x), dried cherries (4.0x), cherry juice (1.5x), dried peaches (7.0x), dried plums (5.0x), and plum/prune juice (1.4x). The processing factors are default values from DEEM.

As shown in the following table, the resulting dietary food exposures occupy up to 37.6% of the chronic population adjusted dose (PAD) for the most highly exposed population subgroup, children 1 to 6 years old. These results should be viewed as conservative (health protective) risk estimates. Refinements such as use of percent crop-treated information and/or anticipated residue values would yield even lower estimates of chronic dietary exposure.

SUMMARY: CHRONIC DIETARY EXPOSURE ANALYSIS BY DEEM (TIER 1)

Population subgroup	Exposure milligram/ kilogram/day (mg/kg/day)	Percent of chronic PAD
U.S. population—48 contiguous States	0.0189	18.9
All infants (<1–year)	0.0315	31.5
Nursing infants <1–year old	0.0134	13.4
Non-nursing infants <1–year old	0.0368	36.8
Children 1 to 6 years old	0.0376	37.6
Children 7 to 12 years old	0.0216	21.6
Females 13+ (nursing)	0.0156	19.1
U.S. population (autumn season)	0.0191	19.1
U.S. population (spring season)	0.0190	19.0
Northeast region	0.0206	20.6
Western region	0.0210	21.0
Hispanics	0.0191	19.1
Non-Hispanic/ non-white/ non-black	0.0249	24.8

Percent chronic PAD = (Exposure divided by chronic PAD) x 100%.

The subgroups listed are:

1. The U.S. population (total).
2. Those for infants and children.
3. The other subgroup(s), if any, for which the percentage of the chronic PAD occupied is greater than that occupied by the subgroup U.S. population (total).
4. The most highly exposed of the females subgroups (in this case, females, (13+ years, nursing).

ii. *Drinking water.* There are no water-related exposure data from monitoring to complete a quantitative drinking water exposure analysis and risk assessment for methoxyfenozide. Generic expected environmental concentration (GENEEC) and/or EPA's pesticide root zone model/exposure analysis modeling system (PRZM/EXAMS) (both produce estimates of pesticide concentration in a farm pond) are used to generate estimated environmental concentrations (EECs) for surface water and screening concentration in ground water (SCI-GROW) (an empirical model based upon actual monitoring data collected for a number of pesticides that serve as benchmarks) predicts EECs in ground water. These models take into account the use patterns and the environmental profile of a pesticide, but do not include consideration of the impact that processing 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 at this stage is to provide a coarse screen for assessing whether a pesticide is likely to be present in drinking water at concentrations which would exceed human health levels of concern.

A drinking water level of comparison (DWLOC) is the concentration of a pesticide in drinking water that would be acceptable as a theoretical upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses. HED uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for a pesticide, the DWLOC is used as a point of comparison against the conservative EECs provided by computer modeling (SCI-GROW, GENEEC, PRZM/EXAMS).

a. *Acute exposure and risk.* Because no acute dietary endpoint was determined, Rohm and Haas concludes that there is a reasonable certainty of no harm from acute exposure from drinking water.

b. *Chronic exposure and risk.* Tier II screening-level assessments can be conducted using the simulation models SCI-GROW and PRZM/EXAMS to generate EECs for ground and surface water, respectively. The modeling was conducted based on the environmental profile and the maximum seasonal application rate proposed for methoxyfenozide (1.0 lb ai/acre/season). PRZM/EXAMS was used to generate the surface water EECs, because it can factor the persistent nature of the chemical into the estimates.

The EECs for assessing chronic aggregate dietary risk used by HED are 6 parts per billion (ppb) (in ground water, based on SCI-GROW) and 98.5 parts per billion (ppb) (in surface water, based on the PRZM/EXAMS, long-term mean).The back-calculated DWLOCs for

assessing chronic aggregate dietary risk range from 624 ppb for the most highly exposed population subgroup (children 1 to 6 years old) to 2,839 ppb for the U.S. population (48 contiguous States—all seasons).

The SCI-GROW and PRZM/EXAMS chronic EECs are less than the Agency's level of comparison (the DWLOC value for each population subgroup) for methoxyfenozide residues in drinking water as a contribution to chronic aggregate exposure. Rohm and Haas thus concludes with reasonable certainty that residues of methoxyfenozide in drinking water will not contribute significantly to the aggregate chronic human health risk and that the chronic aggregate exposure from methoxyfenozide residues in food and drinking water will not exceed the Agency's level of concern (100% of the chronic PAD) for chronic dietary aggregate exposure by any population subgroup. EPA generally has no concern for exposures below 100% of the chronic PAD, because it is a level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to the health and safety of any population subgroup. This risk assessment is considered high confidence, conservative, and very protective of human health.

DWLOC FOR CHRONIC EXPOSURE TO METHOXYFENOZIDE

Population subgroup	Chronic PAD (mg/kg/day)	Food exposure (mg/kg/day)	Maximum water exposure (mg/kg/day)	SCI-GROW (µg/L)	GENEEC 56–day Average (µg/L)	DWLOC (µg/L)
U.S. population–48 contiguous states		0.0189	0.0811			2,839
Females 13+ (nursing)		0.0191	0.0809			2,427
Non-nursing infants <1–year old	0.10	0.0368	0.0632	6	98.5	632
Children 1 to 6 years old		0.0376	0.0624			624
Children 7 to 12 years old		0.0216	0.0784			784

Notes: Maximum water exposure (mg/kg/day) = chronic PAD (mg/kg/day) - chronic food exposure. DWLOC (µg/L) = (Maximum water exposure (mg/kg/d) x body weight (kg)) divided by (1/1,000 mg/µg x water consumed daily (L/day)). Body weights (kg) for adults is 70, for females 13+ is 60 kg and for all children is 10 kg. Drinking water consumption is 2 liters per day for adults and 1 liter per day for children.

2. *Non-dietary exposure.* Methoxyfenozide is not currently registered for use on any residential non-food sites. Therefore, there is no non-dietary acute, chronic, short- or intermediate-term exposure.

D. Cumulative Effects

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 methoxyfenozide 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, methoxyfenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, it is assumed that methoxyfenozide does not have a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population.* Using the DEEM exposure assumptions described in this unit, Rohm and Haas has concluded that aggregate exposure to methoxyfenozide from food will utilize 18.9% of the chronic PAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children 1 to 6 years old at 37.6% of the chronic PAD and is discussed below. EPA generally has no concern for exposures below 100% of the chronic PAD because the chronic PAD 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 methoxyfenozide in drinking water, the aggregate exposure is not expected to exceed 100% of the chronic PAD. Rohm and Haas concludes that there is a reasonable certainty that no harm will result from aggregate exposure to methoxyfenozide residues.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of methoxyfenozide, 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 during 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 ten-fold 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 (UF) (usually 100 for combined interspecies and intraspecies variability) and not the additional ten-fold MOE/UF 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.

The toxicology data base for methoxyfenozide included acceptable developmental toxicity studies in both rats and rabbits as well as a 2–generation reproductive toxicity study in rats. The data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to methoxyfenozide. There is a complete toxicity data base for methoxyfenozide and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on the completeness of the data base and the lack of prenatal and postnatal toxicity, EPA determined that an additional safety factor was not needed for the protection of infants and children.

Since no acute toxicological endpoints were established, acute aggregate risk is considered to be negligible. Using the exposure assumptions described in this unit, Rohm and Haas has concluded that aggregate exposure to methoxyfenozide from food will utilize 37.6% 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 methoxyfenozide in drinking water, Rohm and Haas does not expect the aggregate exposure to exceed 100% of the cPAD. Short and intermediate term risks are judged to be negligible due to the lack of significant toxicological effects observed. Based on these risk assessments, Rohm and Haas concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to methoxyfenozide residues.

F. International Tolerances

There are no established or proposed Codex, Canadian or Mexican limits for residues of methoxyfenozide in/on plant or animal commodities. Therefore, no compatibility issues exist with regard to the proposed U.S. tolerances.

[FR Doc. 01–12904 Filed 5–22–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–50885; FRL–6777–9]

Issuance of an Experimental Use Permit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted an experimental use permit (EUP) to the following pesticide applicant. An EUP permits use of a pesticide for experimental or research purposes only in accordance with the limitations in the permit.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Mandula, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Office location, telephone number, and e-mail address: 1921 Jefferson Davis Hwy., Rm. 9016, Crystal Mall #2, Arlington, VA; (703) 308–7378; e-mail address: mandula.barbara@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this action, consult the designated contact person listed for the individual EUP.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

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,'' ''Regulations and Proposed Rules,'' 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/.

II. EUP

EPA has issued the following EUP:

73417–EUP–1. Issuance. Greenville Farms, 1689 N. 1200 E. Logan, Utah 84341. This EUP allows the use of 83 pounds of the herbicide dyers woad rust on 12 acres of rangeland to evaluate the control of dyers woad. The program is authorized only in the State of Utah. The EUP is effective from March 1, 2001 to March 1, 2002.

Persons wishing to review this EUP are referred to the designated contact person. Inquiries concerning this permit should be directed to the person cited above. It is suggested that interested persons call before visiting the EPA office, so that the appropriate file may be made available for inspection purposes from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Experimental use permits.

Dated: May 2, 2001.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 01–12902 Filed 5–22–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6982–8]

Massachusetts Marine Sanitation Device Standard; Receipt of Petition

Notice is hereby given that a petition has been received from the State of Massachusetts requesting a determination of the Regional Administrator, U.S. Environmental Protection Agency, pursuant to section 312(f)(3) of Public Law 92–500 as amended by Public Law 95–217 and Public Law 100–4, that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for the Three Bay/Centerville Harbor Area in the Town of Barnstable, County of Barnstable, State of Massachusetts, to qualify as a ''No Discharge Area'' (NDA). The areas covered under this petition include Cotuit Bay, West Bay, East Bay, and Squaw Island Marsh, north of a line drawn 500 feet south of their mouths at Nantucket Sound. The area also includes the following sub-embayments: North Bay, Prince Cove, Marstons Mills River South of Route 28, Scudder Bay South of Bumps River Road, Bumps River East of Bumps River Road, Centerville River West of Craigville Beach Road, and Halls Creek South of