RfD. This is particularly relevant in that this assessment assumed tolerance level residues for all crops (0.02 ppm for tomatoes and peanuts, 0.03 ppm for potatoes and 0.05 ppm for bananas and coffee). Indeed, when anticipated residues are used estimated exposure is less than 2% of the RfD for all population groups.

A similar situation applies to acute exposure (and risk) from the proposed uses. For tomatoes, potatoes and peanuts, the highest exposed subgroup is all infants 1 year old, with an acute exposure of 0.000479 mg/kg bwt/day at the 95th percentile for consumers only. This results in a MOE of 8,300, which exceeds the traditional level considered to provide adequate protection by nearly two orders of magnitude. When residues on bananas and coffee beans are included in the assessment, children 1-6 yrs have an estimated acute exposure at the 95th percentile of 0.000588 mg/kg bwt/day, which results in an MOE of 6,800. Again, when anticipated residues, as calculated for acute exposure (i.e., the highest field trial residue), are used in the assessment for all the proposed crops, the highest exposure is only 0.000456 mg/kg bwt/day at the 95th percentile, with an MOE of 8,700 for all infants (consumers only). Indeed MOE's at the 99.9th percentile of exposure are far higher than generally is considered to be safe by the agency for all population subgroups.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions and the proposed RfD and acute NOEL described above, dietary exposure was calculated.

As discussed above, even under the ''worst-case'' chronic exposure scenario, a very small portion of the RfD was used. When anticipated residues for tomatoes, potatoes and peanuts are used in the chronic dietary exposure assessment, the estimated exposure is 0.000068 mg/kg bwt/day, for the total U.S. population (or 1.7% of the RfD). When bananas and coffee beans are included in the assessment, the estimated exposure is 0.000083 mg/kg bwt/day for the total U.S. population (or 2.0% of the RfD).

The acute exposure estimates clearly indicate that exposures provide adequate MOEs at the 95th percentile of exposure. The U.S. population has an estimated 95th percentile exposure value of 0.000246 mg/kg bwt/day, equivalent to an MOE of 16,000 for tomatoes, potatoes and peanuts. When bananas and coffee are included in the assessment, the estimated 95th percentile exposure for the total U.S. population is 0.000279 mg/kg bwt/day, which results in an MOE of 14,000. These values are more than 2 orders of magnitude higher than a level considered to provide adequate protection. The exposure estimate for fosthiazate when highest field trial residue is used is 0.000187 mg/kg bwt/day, representing an MOE of 21,000, including all crops. Therefore, since there are no other avenues of exposure (see aggregate exposure section of this document) ISK Biosciences Corporation concludes that there is a reasonable certainty that no harm will result from aggregate exposure to fosthiazate residues from use on tomatoes, potatoes, peanuts, bananas and coffee.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of fosthiazate, data from developmental toxicity studies and other appropriate studies are considered. ISK Biosciences Corporation calculates that children 1–6 (the highest exposed subgroup) have an estimated chronic dietary exposure of 0.000132 mg/kg bwt/day, which represents only 3.2% of the RfD using worst case assumptions. When bananas and coffee beans are included, these estimates are 0.000173 mg/kg bwt/day and 4.2% of the RfD for children 1–6. When anticipated residues are used in calculating chronic dietary exposure, only 1.1% of the RfD is consumed for this population subgroup and 1.3% of the RfD after bananas and coffee are included in the assessment. Acute exposure estimates similarly show no concern as all infants 1 year of age (the highest exposed subgroup) have MOEs of 8,300 even when using worst case assumptions. When bananas and coffee are included in the assessment, children 1–6 years (the highest exposed subgroup) have an MOE of 6,800. Therefore, since there are no other avenues of exposure other than dietary, there is reasonable certainty that no harm will result to infants and children from aggregate exposure to fosthiazate from use on tomatoes, potatoes, peanuts, bananas and coffee.

F. International Tolerances

There are no Codex maximum residue levels established for residues of fosthiazate.

[FR Doc. 01–28739 Filed 11–20–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1044; FRL–6802–2]

Notice of Filing of Pesticide Petitions to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions 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–1044, must be received on or before December 21, 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–1044 in the subject line on the first page of your response.

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

2. *In person.* The Agency has established an official record for this action under docket control number PF–1044. 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 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.

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–1044 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 Hwy., 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–1044. 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 persons listed 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 the following pesticide petitions 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 these pesticide petitions contain data or information regarding the elements set forth in section 408(d)(2) of FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of these pesticide petitions. Additional data may be needed before EPA rules on these pesticide petitions.

List of Subjects

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

Dated: October 17, 2001.

Janet L. Andersen,

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

Summary of Petitions

The petitioner summary for each pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the pesticide petition was prepared by the petitioner and represents the view of the petitioner. The pesticide 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.

I. SciReg, Inc./Micro Flo Company

PP 1F6324

EPA has received a pesticide petition 1F6324 from SciReg, Inc., on behalf of Micro Flo Company, 12733 Director's Loop, Woodbridge, VA 22192, proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an amendment/expansion of an existing tolerance exemption for the microbial pesticide *Bacillus cereus* strain BP01 in or on all raw agricultural commodities.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, SciReg, Inc., on behalf of Micro Flo Company has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by SciReg, Inc., on behalf of Micro Flo Company and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product Name and Proposed Use Practices

Micro Flo Company's *Bacillus cereus* strain BPO1 is a foliar-applied plant regulator. When combined with the plant growth regulator, mepiquat chloride, for use on cotton, it allows the grower to manage the cotton plant for short-season production leading to reduced risk of yield and quality loss due to delayed and prolonged harvest. Benefits derived from BPO1 in conjunction with mepiquat chloride include increased early boll retention and/or larger bolls, reduced plant height which provides a more open canopy, less boll rot, improved defoliation, less trash and lower ginning costs, better harvest efficiency, and a darker leaf color. Micro Flo is currently exploring the potential use of BPO1 on soybeans.

The maximum application rate for BPO1 on all crops will be less than 2 grams/acre/application and up to 20 grams/acre/year. This tolerance exemption amendment is for use of *Bacillus cereus* strain BPO1 up to 20 grams/acre/year. There is a 30–day pre-harvest interval (PHI). Livestock should not be fed or permitted to graze on BPO1–treated forage.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues*. The ATCC classification of Micro Flo's *Bacillus cereus* strain BPO1 is 55675. Only residues of BPO1 would be present, and these residues are indistinguishable from naturally occurring *Bacillus cereus* without using specific genetic testing procedures for differentiating them.

2. *Magnitude of residue at the time of harvest and method used to determine the residue*. No magnitude of residue studies have not been conducted on BPO1 as total application rates are exceedingly low, cotton: average, 0.2 gram BPO1/acre/year; maximum, 0.75 gram/acre/year; soybeans and other crops: 20 gram BPO1/acre/year and it is toxicologically innocuous. The PHI is currently 30 days. *Bacillus cereus* is indigenous and widespread throughout the United States and the rest of the world.

3. *Analytical method*. As indicated above, the naturally occurring population of *Bacillus cereus* make it impossible to distinguish between natural and introduced microbial populations without utilizing genetic differentiation techniques and therefore to establish and enforce tolerances for BPO1. In addition, the PHI interval is currently 30 days.

C. Mammalian Toxicological Profile

Acute mammalian toxicity studies via oral, dermal, inhalation, eye, intratracheal, and intravenous routes were conducted with *Bacillus cereus* strain BPO1. No pathogenicity was observed. BPO1 was also tested for entero-toxin and emetic-toxin production; no toxins were detected. In a blood agar hemolysis assay conducted with BPO1, weak alpha hemolysis was observed. Based on the results of the above studies, subchronic, reproductive, teratology, chronic, and mutagenicity studies were not deemed necessary.

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. *Bacillus cereus* strain BPO1 is currently registered for use on cotton at rates up to 0.75 gram/acre/year. Micro Flo Company is currently evaluating BPO1 for future registration for use on soybeans and other crops (e.g., corn) at rates up to 20 gram/acre/year. Considering the extremely low application rates, the potential dietary exposure to BPO1 is minuscule.

ii. *Drinking water*. *Bacillus cereus* strain BP01 is prohibited on the label from direct application to water, and is not a known aquatic bacterium, and therefore is not expected to proliferate in aquatic environments. Typical agricultural practices are carried out such that spray drift is minimal. Although possible minimal spray drift may contact drinking water, both soil percolation and municipal drinking water treatment processes would further reduce or eliminate the possibility of exposure via potable water. Again, considering the extremely low application rates, the minimal toxicity, lack of pathogenicity and infectivity, and plant regulator mode of action versus the insecticidal or fungicidal properties of other *Bacillus products*, the potential drinking water exposure to and toxic potential of BP01 are minuscule.

2. *Non-dietary exposure*. There is no anticipated non-dietary exposure to *Bacillus cereus* strain BPO1. Contact with naturally occurring populations of *Bacillus cereus* is common throughout the world, and residue exposure through contact with BPO1-treated crops has been theoretically considered. Based on the absence of toxicity, infectivity, pathogenicity, and mode of action of BPO1, residues that may be present are unlikely to be of concern.

E. Cumulative Exposure

Although there are other currently registered *Bacillus cereus*, *Bacillus subtilis* and *Bacillus thuringiensis* products, some of which hold tolerance exemptions, their modes of action are unlike BP01. Specifically, the other products typically produce toxin which, when the bacteria producing it is consumed by insect pests, causes the pest to die. As previously indicated, BP01 does not produce toxin (diarrheal or emetic), but instead appears to enable the target plant to more readily and

efficiently uptake and utilize growth nutrients. BP01 is a true growth regulator and to our knowledge does not have classic pesticidal activity. Based on the above, it is therefore felt that BP01 should not be considered similar to existing *Bacillus* products.

F. Safety Determination

1. *U.S. population*. Since the maximum current use rate is 0.75 gram BPO1/acre/year for use on cotton and 20 gram/acre/year on soybeans and other crops for which registration applications have not yet been submitted, the associated anticipated minute residue levels are extremely unlikely to add appreciably to the natural, indigenous background levels of *Bacillus cereus*. BPO1 does not produce enterotoxin, diarrheal or emetic, and the toxicity/pathogenicity/infectivity studies show virtually no negative effects, BPO1 should be considered safe when used on raw agricultural commodities and meets the reasonable certainty of no harm requirement.

2. *Infants and children*. As previously discussed, based on the quantities of BPO1 used, its lack of toxicity and pathogenicity, and its mode of action, it is exceedingly improbable that infants or children would be at greater risk to BPO1 exposure than would adults. BPO1 should be considered safe when used on raw agricultural commodities and meets the reasonable certainty of no harm requirement.

G. Effects on the Immune and Endocrine Systems

There are no known effects on the immune and endocrine systems, nor are any effects expected. *Bacillus cereus* strain BP01 is not structurally related to any known neurotoxins or endocrine disruptors. Additionally, per the Agency's Registration Eligibility Document for *Bacillus cereus* strain BP01, July 1997):

> There is no known metabolite that acts as an endocrine disrupter produced by this microorganism. The toxicity/pathogenicity studies in the rodent required for microbial pesticides indicate that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient. Therefore, no adverse effects to the endocrine or immune systems are known or expected.

H. Existing Tolerances

There is currently a tolerance exemption for *Bacillus cereus* strain BPO1 at 40 CFR 180.1181 for residues in or on cottonseed.

I. International Tolerances

There are no Codex Maximum Residue Levels or tolerance exemptions for *Bacillus cereus* strain BPO1.

II. Platte Chemical Company

PP 1F6316

EPA has received a pesticide petition [1F6316] from Platte Chemical Company, 419 18h Street, Greeley, CO 80632, proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180, to establish an exemption from the requirement of a tolerance for the biochemical pesticide diallyl sulfides (DADs).

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Platte Chemical Company has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Platte Chemical Company and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product Name and Proposed Use Practices

DADs are proposed for use as a soil fumigant solution for the control of white rot (*Sclerotium cepivorum*) in onions, garlic, shallots and leeks. The end-use product (trade name: Alli-Up) contains 90% DADs in a liquid formulation (8.3 lb of active ingredient per gallon). Application is recommended for any field that shows evidence or has a history of white rot infestations. When applied to infected soils in conjunction with a rotational crop, DADs will mimic the presence of an Allium crop, which will in turn stimulate the germination of white rot spores (*sclerotia*). The germinated spores will subsequently perish since no host crop is present. The product is applied through conventional soil fumigation equipment such as an enclosed shanking system.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues*. Diallyl Sulfides (DADs). DADs consist of 86.90% diallyl disulfide, 8.90% diallyl monosulfide, 3.90% diallyl trisulfide, and 0.30% diallyl tetrasulfide. DADs are a composite of diallyl sulfides and exists in a state of dynamic equilibrium. Diallyl disulfide CAS No. 2179–59–9; dially sulfide (monosulfide) CAS No. 592–88–1; diallyl trisulfide CAS No. 2050–87–5; diallyl tetrasulfide CAS No. 2444–49–7.

2. *Magnitude of residue at the time of harvest and method used to determine the residue*. Residues of DADs are not expected on agricultural commodities.

3. *Analytical method*. An analytical method for residues is not applicable. Residues of DADs are not expected on agricultural commodities.

C. Mammalian Toxicological Profile

DADs are found naturally in allium crops, including onions and garlic. The acute oral toxicity LD_{50} (rat) of technical DADs are 346 mg/kg. The acute dermal toxicity LD_{50} (rabbit) is 1,967 mg/kg. DADs are considered a moderate eye irritant to the ocular tissue of the rabbit; primary irritation index was found to be 5.42. Dermal irritation is severe to the skin of the rabbit. DADs were found to be a dermal contact sensitizer in guinea pigs. Diallyl disulfide, the main component of DADs, was not mutagenic in an Ames test using *Salmonella typhimurium* strain TA100 with and without S-9 activation. A waiver has been requested for acute inhalation toxicity based on the fact that DADs will be applied by soil injection via an enclosed-cab method of application. Because it is composed of diallyl sulfides that are found in garlic and other allium crops, DADs have an extremely strong, obnoxious odor. As such, every effort will be taken to ensure that mixers and handlers have minimal inhalation potential. Personal protective equipment and the method of application mitigates the potential for exposure. In addition, a waiver has been requested for immunotoxicity based on the fact that no immunotoxic effects, such as induced dysfunction or inappropriate suppressive or stimulatory responses in components of the immune system of test animals, are known, have been reported, or are expected from DADs.

Results from acute toxicological testing show test animals displaying symptoms of hemolytic anemia when exposed to DADs. Hemolytic anemia has been documented for both livestock and laboratory test animals fed either DADs, onion or garlic. Both onion and garlic are rich in DADs and other sulfur containing analogs. Hemolytic anemia results in a reduction of red blood cells and consequently a reduction in the amount of oxygen available to the central nervous system of treated susceptible animal species, such as rats and rabbits. There are no reported incidents of humans experiencing hemolytic anemia following

consumption of either allium crops or DADs enriched products, such as garlic oils and pills. Extensive medical research has shown that garlic is considered a beneficial food with possible medicinal value.

A study done on the antimutagenic activities of garlic extract for the purpose of cancer research indicates that aqueous garlic extract possesses antimutagenic properties toward ionizing radiation, peroxides, adriamycin and N-methyl-N'-nitro-nitroguanidine. Results obtained with garlic extract in preliminary experiments with Chinese hamster ovary cells suggest that the antimutagenic properties of garlic extract were not restricted to prokaryotic cells. Diallyl sulfide and diallyl disulfide were found to have clastogenic activity in a Chinese hamster ovary cell assay and was considered to have potential carcinogenic activity. However, further analysis found that these two compounds might not present a tumorigenic hazard *in vivo* if consumed as part of a normal diet. Diallyl sulfide was found to be among the most effective agents in inhibiting the expression of benzo[a]pyrene-induced nucleotoxicity in the colon. Rats fed 5 mL of raw garlic extract per kg body weight in a prolonged feeding study either died or experienced anemia, weight loss, and retarded growth. Long-term chronic garlic powder administration to rats significantly reduced serum/liver cholesterol, serum triglycerides, phospholipids and transaminase enzyme activity. Garlic has been shown to have a potential reversal effect on the risk of stomach cancer. Research suggests that the antitumor effect of DADs is due to its ability to alter cancer-cell sulfur compounds linked to cell division. Research also suggests that aged garlic extract and its constituents have demonstrated anti-cancer effects in an array of cancer models. There have been no incidents of hypersensitivity reported by researchers, manufacturers or users of Alli-Up or DADs, when used for agricultural purposes.

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Dietary exposure from use of DADs, as proposed, is minimal. DADs are applied to the soil by closed system soil injection, they are not applied to growing crops directly. Residues of DADs are not expected on agricultural commodities. DADs are volatile compounds, and tend to move more readily through dry soils at higher soil temperatures. When applied according to label directions, the effective duration of response to DADs is approximately 2.5 months at temperatures of 48 to 70 °F. The class of diallyl sulfides that make up DADs is ubiquitous in garlic and garlic products, such as garlic pills (non-prescription diet or herbal supplements). DADs may also be present as an added food flavoring ingredients. The estimated upper limit for human intake of garlic is reported to be 5.5 g/day, which is equivalent to 3.3 mg/day of DADs. Researchers have measured up to 2.39 mg/g of DADs and related compounds in steam distilled commercial garlic products.

ii. *Drinking water*. Similarly, exposure to humans from residues of DADs in consumed drinking water would be unlikely. DADs are volatile compounds applied to the soil by closed system soil injection; they are not applied to growing crops directly. Potential exposure to surface water would be negligible and exposure to drinking water (well or ground water) would be impossible to measure.

2. *Non-dietary exposure.* The potential for non-dietary exposure to the general population, including infants and children, is unlikely as the proposed use sites are agricultural settings. However, non-dietary exposures would not be expected to pose any quantifiable risk due to a lack of residues of toxicological concern. Personal protective equipment (PPE) mitigates the potential for exposure to applicators and handlers of the proposed products, when used in agricultural settings.

E. Cumulative Exposure

It is not expected that, when used as proposed, DADs would result in residues that would remain in human food items. Levels of exposure resulting from the proposed use of DADs would be significantly lower than those found in the general population's consumption of onion and garlic foods (raw, cook and processed) and diet/herbal supplement products. PPE will mitigate the potential for exposure to applicators and handlers of the proposed product, when used in agricultural settings.

F. Safety Determination

1. *U.S. population*. DADs are applied to the soil, they are applied to growing crops directly. Residues of DADs are not expected on agricultural commodities, and therefore, exposure to the general U.S. population, from the proposed uses, is not anticipated. The class of diallyl sulfides that make up DADs is already ubiquitous in garlic and garlic products, such as garlic pills (non-prescription diet or herbal supplements).

2. *Infants and children*. As mentioned above, residues of DADs are not expected on agricultural commodities. There is a reasonable certainty of no harm for infants and children from exposure to DADs from the proposed uses.

G. Effects on the Immune and Endocrine Systems

To date there is no evidence to suggest that DADs act as an endocrine disrupter. Research on garlic powder has suggested an antiandrogenic activity of garlic on rats. Adult male rats gavaged daily with 50 mg of garlic powder, and sacrificed at 45 and 70 days displayed reduced testicular function. Except for the garlic powder effect on rat testes, no further information suggests DADs will adversely affect the immune or endocrine system in humans and other mammals, or any other animal system.

H. Existing Tolerances

There is no U.S. EPA tolerance. DADs are listed in 21 CFR 172.515 by the Food and Drug Administration (FDA) as an approved direct food additive. Additionally, DADs were given Generally Recognized as Safe (GRAS) status No. 2028, 1965 by the FDA. The Council of Europe (1981) has included it in the list of substances that may be added to food without a hazard to public health.

I. International Tolerances

There is no Codex Alimentarium Commission Maximum Residue Level for DADs.

[FR Doc. 01–28740 Filed 11–20–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–00731; FRL–6792–9]

Pesticide Science Policies: Water Treatment Effects on Pesticide Removal and Transformation; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: To assure that EPA's policies related to implementing the Food Quality Protection Act of 1996 (FQPA) are transparent and open to public participation, EPA is soliciting comments on the pesticide draft science policy document entitled ''The Incorporation of Water Treatment