developed as part of EPA's process for making reregistration eligibility decisions for the organophosphate pesticides and for tolerance reassessments consistent with the FFDCA, as amended by the FQPA. The Agency's preliminary dichlorvos (DDVP) risk assessments for the following dichlorvos (DDVP) organophosphate pesticides are available in the individual organophosphate pesticide dockets.

Included in the individual organophosphate pesticide dockets are the Agency's preliminary risk assessments. As additional comments, reviews, and risk assessment modifications become available, these will also be docketed for the dichlorvos (DDVP) organophosphate pesticides listed in this notice. The Agency cautions that these risk assessments are preliminary assessments only and that further refinements of the risk assessments will be appropriate for some, if not all, of these dichlorvos (DDVP) organophosphate pesticides. These documents reflect only the work and analysis conducted as of the time they were produced and it is appropriate that, as new information becomes available and/or additional analyses are performed, the conclusions they contain may change.

As the preliminary risk assessments for the remaining organophosphate pesticides are completed and registrants are given a 30-day review period to identify possible computational or other clear errors in the risk assessment, these risk assessments and registrant responses will be placed in the individual organophosphate pesticide dockets. A notice of availability for subsequent assessments will appear in the **Federal Register**.

The Agency is providing an opportunity, through this notice, for interested parties to provide written comments and input to the Agency on the preliminary risk assessments for the chemicals specified in this notice. Such comments and input could address, for example, the availability of additional data to further refine the risk assessments, such as percent crop treated information or submission of residue data from food processing studies, or could address the Agency's risk assessment methodologies and assumptions as applied to these specific chemicals. Comments should be limited to issues raised within the preliminary risk assessments and associated documents. EPA will provide other opportunities for public comment on other science issues associated with the organophosphate pesticide tolerance reassessment program. Failure to comment on any such issues as part of this opportunity will in no way prejudice or limit a commenter's opportunity to participate fully in later notice and comment processes. All comments should be submitted by December 11, 2000 using the methods in Unit I. of the **SUPPLEMENTARY INFORMATION**. Comments will become part of the Agency record for each individual organophosphate pesticide to which it pertains.

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: October 3, 2000.

Jack E. Housenger,

Acting Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 00–26067 Filed 10–10–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–979; FRL–6749–6]

Notice of Filing a Pesticide Petition 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 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–979, must be received on or before November 13, 2000.

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–979 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6304; e-mail address: boyle.kathryn@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,'' ''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–979. 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–979 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–979. 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 Comestic 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: September 29, 2000.

James Jones,

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.

Avecia Biocides

PP 0F6172

EPA has received a pesticide petition (PP 0F6172) from Avecia Biocides, 1405 Foulk Road P.O. Box 15457 Wilmington, DE 19859 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 1,2 benzisothiazoline-3-one (BIT) when used as a preservative/stabilizer in pesticide formulations applied to animals. 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. *Analytical method.* Because Avecia Biocides is petitioning for an exemption from the requirement of a tolerance, an enforcement analytical method for BIT is not needed.

2. *Magnitude of residues.* Based on the proposed amount of BIT to be used in the final products (0.1% or less of the total formulation) and the recommended frequency and rates of application to the animals, the residues in treated animals are expected to be essentially undetectable and not toxicologically significant.

B. Toxicological Profile

1. *Acute toxicity.* The acute oral toxicity of technical BIT is relatively low by oral and dermal exposure. The

acute oral median lethal dose (MLD) of the technical is 700–800 milligrams/kilograms (mg/kg) (toxicity category III) in rats and the acute dermal LD_{50} in rats is >2,000 mg/kg (toxicity category III). Technical BIT is slightly irritating to rabbit skin following a single 4 hour exposure and an abbreviated rabbit eye irritation study showed technical BIT to be a severe eye irritant. In skin sensitization studies using guinea pigs, technical BIT was shown to be a moderate skin sensitizer under the conditions of the test.

2. *Genotoxicty*. Generally, BIT is non-mutagenic in the Ames test with and without metabolic activation. In cases where the Ames test has produced positive responses the responses are either not reproducible or lack a dose response effect. In a L5178Y mouse lymphoma cell test, BIT produced a negative response both in the presence and absence of S9 activation, indicating it is non-mutagenic in mammalian cells. Negative responses were also seen *in vitro* in a DNA repair assay. In an *in vivo* mouse bone marrow micronucleus assay, BIT produced a negative response, indicating that it was not cytotoxic to bone marrow cells. BIT did not induce unscheduled DNA synthesis in rat hepatocytes. The conclusion from the results of these various assays is that BIT presents no significant genotoxic hazard, either *in vitro* or *in vivo*.

3. *Reproductive and developmental toxicity*. In a rat teratology study, doses up to 100 mg/kg/day of the technical BIT administered from days 7–16 of gestation did not cause any teratogenic effects. The highest dose level was maternally toxic and was marginally toxic to the fetuses. The no observed adverse effect level (NOAEL) for fetal toxicity was 40 mg/kg/day and 10 mg/kg/day for maternal toxicity.

4. *Subchronic toxicity*. NOAELs for BIT have been determined in 2 subchronic studies. In a 90 day feeding study conducted with rats in which the animals received 0, 200, 900, or 4,000 ppm of BIT technical paste in the diet, the only toxic effects observed occurred in the high dose animals and consisted of decreased body weights (bwts) (both sexes) and reduced food consumption (females). Hyperplasia of the fore stomach observed histopathologically in high dose animals was considered to be due to irritation by the test material. The toxicological NOAEL was 900 parts per million (ppm) (about 74 mg/kg/day).

In another subchronic study, male and female beagle dogs (4 animals sex/dose) were dosed orally for 90 days with 0, 5, 20, or 50 mg/kg/day of the BIT technical paste in corn oil. No toxicologically significant effects were seen in any dose group, resulting in a toxicological NOAEL of 50 mg/kg/day. The absolute NOAEL in the study was 5 mg/kg/day.

5. *Chronic toxicity*. Although no chronic studies have been conducted on BIT, the proposed use of BIT as an inert ingredient (preservative/stabilizer) in pesticide products applied to animals is not expected to create or result in chronic exposure to humans. The combined results from various mutagenicity studies indicate that BIT is not genotoxic. The effects noted in the subchronic studies in both rats and dogs did not indicate concern for potential chronic toxicity. Since BIT is not structurally similar to a known carcinogen, all current available evidence indicates that BIT would not be carcinogenic.

6. *Animal metabolism*. Rats administered radiolabelled BIT by gavage showed that most (86%) of the radioactivity was excreted within 24 hours. A total of 96% (91% in urine, 5% in feces) was excreted in 5 days. Analysis of abdominal fat after repeated dosing with BIT showed no accumulation of BIT or any of its metabolites. In another study comparing the metabolism of BIT in the rat and dog, the routes of metabolism in the 2 species were shown to be essentially similar. Breakdown of BIT by both species was rapid and was carried essentially to completion since no unchanged BIT was found in either rat or dog urine.

7. *Metabolite toxicology*. Metabolism studies in both the rat and dog showed that BIT was rapidly and completely metabolized by both species. The metabolites identified included o-(methylsulphinly)benzamide, and o-(methylsulphonyl)benzamide. The studies showed there were no significant accumulation of BIT or its metabolites in either species. There are, therefore, no significant concerns regarding the toxicity of BIT or its metabolites.

8. *Endocrine disruption*. BIT does not appear to disrupt (block, enhance, or mimic) normal endocrine function. BIT is not structurally similar to natural hormones, especially estrogens, androgens, and thyroid hormones.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Based on the toxicity data, an aggregate risk or likelihood of the occurrence of an adverse health effect resulting from all routes of exposure to BIT is not expected. There are not acute toxicological concerns associated with the proposed use of BIT as an inert ingredient in animal pesticide products. An acute dietary risk assessment, therefore, is not required.

Chronic exposure to BIT through food is essentially insignificant. This is illustrated by using cattle as an example because proposed dose rates as well as frequency of dosing will be higher in this species that other potential food source animals such as sheep or swine. The absolute maximum accumulated dose of BIT which could be received by an animal based on the highest number of applications permitted at the highest dose rates would not exceed 280 mg of BIT per year, based on a maximum of 20 applications per animal per year. This is assuming 100% of each dose of the pesticide is absorbed through the skin whether it is applied as a pour-on or a spray. For a 500 kg cow this amounts to 0.56 mg/kg BIT per year. Metabolism studies show that 96% of BIT is excreted within 5 days. If it were assumed that the remaining 4% of BIT is not excreted and accumulates in the animal, this would leave 0.022 mg/kg BIT per animal. Assuming a maximum dietary intake of 16 ounces of beef per day, an average 70 kg adult would ingest 0.01 mg of BIT, which is 0.0001 mg/kg per day. A 28 kg child consuming an average of 4 ounces of beef per day would ingest 0.002 mg of BIT per day, which is 0.00007 mg/kg/day. These calculations indicate that levels of BIT in the diet resulting from its proposed use in animal pesticide products are essentially insignificant in both adults and children, even when highly exaggerated levels of product absorption and food consumption are used in the calculations. It is assumed that infants will not be consuming any beef. Potential exposure to BIT through milk consumption, even to children during the years of highest consumption of cows' milk, is considered to be negligible.

ii. *Drinking water*. Contamination of drinking water would not be expected to occur under the proposed use conditions of BIT as an inert preservative/stabilizer in very low concentrations in pesticide products intended for topical applications only. The end use product would be applied principally to cattle and other domestic animals as either a direct pour-on application or as a spray. Neither method of application is expected to contaminate water supplies intended for human consumption.

2. *Non-dietary exposure*. The proposed use of BIT as a preservative/stabilizer in end-use animal pesticide formulations is not expected to result in any significant non-dietary exposure due to the low concentration of BIT employed in the formulation and the

extremely low probability of significant contact by the general public following animal treatment.

D. Cumulative Effects

The cumulative exposure assessment provides an estimate of the extent to which a defined population is exposed to two or more chemicals that share a common mechanism of toxicity by all relevant routes and from all relevant sources. Essentially all exposure from this proposed use of BIT will occur via the diet in the form of meat consumed from animals treated topically with products intended to control external parasites. As discussed above, the levels consumed should not exceed 0.0001 mg/kg/day for adults and 0.00007 mg/kg/day for children. No additional exposure of the general public is expected from either drinking water or non-dietary sources. Even using extremely conservative assumptions, the calculated exposure levels are so low as to be insignificant. The risk of cumulative effects and/or toxicity from BIT is negligible.

E. Safety Determination

1. *U.S. population*. No adverse effects of any kind would be expected from the extremely low dietary levels of BIT that may result from the proposed use of BIT in animal pesticide formulations.

2. *Infants and children*. Nothing in the available literature would suggest that infants and children are more sensitive to the effects of BIT than adults. Since the calculated dietary exposure of children to BIT is even less than adults, this proposed use of BIT should not pose a risk to this population subgroup. Exposure of infants to BIT resulting from its proposed use is expected to be negligible based on the fact that beef is not a normal dietary component for this population. In summary the proposed use of BIT as an inert ingredient in certain animal pesticides formulations will not put infants and children at risk.

F. International Tolerances

No Codex maximum residue levels have been established for BIT.

[FR Doc. 00–25751 Filed 10–10–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–00609A; FRL–6741–2]

The Role of Use-Related Information in Pesticide Risk Assessment and Risk Management

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: EPA announces the availability of the revised version of the pesticide science policy document entitled ''The Role of Use-Related Information in Pesticide Risk Assessment and Risk Management.'' This notice is one in a series concerning science policy documents related to the implementation of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act.

FOR FURTHER INFORMATION CONTACT: Deborah Sisco, Environmental Protection Agency (7503C), 1200 Pennsylvania, Ave., NW., Washington, DC 20460; telephone number: (703) 308–8121; fax number (703) 308–8090; e-mail address: sisco.deborah@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture or formulate pesticides. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of potentially affected entities
Pesticide producers	32532	Pesticide manufacturers Pesticide formulators

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 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 notice affects certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Electronically*. You may obtain electronic copies of this document, the science policy documents, and certain other related documents that might be available from the Office of Pesticide Programs' Home Page at http://www.epa.gov/pesticides. On the Office of Pesticide Programs' Home Page select ''FQPA'' and then look up the entry for this document under ''Science Policies.'' You can also go directly to the listings at the EPA Home page at http://www.epa.gov. On the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry to this document under ''**Federal Register**—Environmental Documents.'' You can go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr.

2. *Fax-on-demand*. You may request a faxed copy of the science policy documents, as well as supporting information, by using a faxphone to call (202) 401–0527. Select item 6069 for the document entitled ''The Role of Use-Related Information in Pesticide Risk Assessment and Risk Management.'' Select item 6070 for the document entitled ''EPA's Responses to Public Comments on the Draft Policy Document.'' You may also follow the automated menu.

3. *In person*. The Agency has established an official record for this action under docket control number OPP–00609A. In addition, the documents referenced in the framework notice, which published in the **Federal Register** on October 29, 1998 (63 FR 58038) (FRL–6041–5) have also been inserted in the docket under docket control number OPP–00557. 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 Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal