Exposure, even at high doses, does not lead to brain cholinesterase inhibition. There is no reliable data to indicate that the effects noted would be cumulative with those of organophosphate or carbamate-type compounds. Therefore, Aventis has considered only the potential risks of ethephon in its exposure assessment.

E. Safety Determination

EPA reference dose (RfD) Peer Review Committee determined that the RfD should be based on the 28–day study in humans. Using the LOAEL of 1.8 mg/kg/day in this study and an uncertainty factor (UF) of 100 to account for intraspecies variability and the lack of a NOAEL, an RfD of 0.018 mg/kg/day was established as the chronic dietary endpoint.

1. *U.S. population.* A chronic dietary risk assessment which included all proposed changes in ethephon tolerances was conducted on ethephon using two approaches: A Tier 1 approach using tolerance-level residues for all foods included in the analysis, and Monte Carlo simulations using tolerance-level residues for all foods adjusted for percent crop treated (PCT) (Tier 3). Using the Tier 1 approach, margin of exposure (MOEs) at the percentiles of exposure for the overall U.S. population were 25 and 9, respectively. Using Tier 3 procedures in which residues were adjusted for the PCT, MOEs were 114 and 42, respectively. Acute exposure was also estimated for infants and children 1 to 6 years of age. In the Tier 1 analysis, the most highly exposed subgroup was infants. For this population, MOEs at the 95th and 99th percentiles of exposure were 7 and 4, respectively. Using the Tier 3 method MOEs were 56 and 12, respectively. Even under the conservative assumptions presented here, the more realistic estimates of dietary exposure (Tier 3 analyses) clearly demonstrate adequate MOEs up to the 99th percentile of exposure for all population groups analyzed.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of ethephon, the available developmental toxicity and reproductive toxicity studies and the potential for endocrine modulation by ethephon were considered. Developmental toxicity studies in two species indicate that ethephon is not a teratogen. The 2 generation reproduction study in rats demonstrated that there were no adverse effects on reproductive performance, fertility, fecundity, pup survival, or pup development. Maternal and developmental NOAELs and LOAELs were comparable, indicating no increase in susceptibility of developing organisms. No evidence of endocrine effects were noted in any study. It is therefore, concluded that ethephon poses no additional risk for infants and children and no additional uncertainty factor is warranted. FFDCA section 408 provides that an additional safety factor for infants and children may be applied in the case of threshold effects. Since, as discussed in the previous section, the toxicology studies do not indicate that young animals are any more susceptible than adult animals and the fact that the proposed RfD calculated from the LOAEL from the 28-day human study already incorporates an additional uncertainty factor, Aventis believes that an adequate margin of safety is, therefore, provided by the RfD established by EPA. Additionally, this LOAEL is also 8X lower than the next lowest NOAEL (2 generation reproduction study, NOAEL=15 mg/kg/day) in the ethephon toxicology data base. Ethephon has no endocrine-modulation characteristics as demonstrated by the lack of endocrine effects in developmental, reproductive, subchronic, and chronic studies.

An RfD of 0.018 mg/kg/day has been established by EPA based on the LOAEL in the 28–day human study. Adequate MOEs exist for all populations including infants and children. No additional uncertainty factor for infants and children is warranted based on the completeness and reliability of the database, the demonstrated lack of increased risk to developing organisms, and the lack of endocrine-modulating effects.

F. International Tolerances

The codex maximum residue limits (MRLs) for grape is 10 mg/kg verses 2 ppm for U.S. tolerance. The tomato codex MRL is 3 mg/kg verses 2 ppm for the U.S. tolerance. All other U.S. tolerances are identical to corresponding codex MRLs.

[FR Doc. 02–19803 Filed 8–6–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0173; FRL–7191–3]

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 ID number OPP–2002–0173, must be received on or before September 6, 2002.

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 ID number OPP–2002–0173 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460;telephone number: (703) 305–7610; e-mail address: jackson.sidney@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 ID number OPP–2002–0173. 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 ID number OPP–2002–0173 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 6.1/8.0/9.0 or ASCII file format. All comments in electronic form must be identified by docket ID number OPP–2002–0173. 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: July 31, 2002.

Peter Caulkins,

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.

Interregional Research Project Number (IR–4)

PP 0E6150

EPA has received a pesticide petition PP (0E6150) from the Interregional Research Project Number (IR-4), Technology Centre of New Jersey, Rutgers, the State University of New Jersey, 681 U. S. Hwy., #1 South, North Brunswick, NJ 08902–3390 proposing, pursuant to section 408(d) of the

FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for combined residues of the herbicide, sethoxydim (2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1- one moiety (calculated as the herbicide)] in or on the raw agricultural commodities as follows:

1. Herb subgroup 19A, fresh leaves, except lemongrass at 5.0 parts per million (ppm).

2. Abarella, atemoya, avocado, acerola, banana, birbira, blimbe, breadfruit, cacao bean canistel, cherimoya, coconut, custard apple, date, durian, feijoa, fig, governor's plum, guava, ilama, imbe, imbu, jaboticaba, jackfruit, kiwifruit, longan, lychee, mamey apple, mango, marmaladebox, mamey sapote, mangosteen, mountain papaya, papaya, passionfruit, persimmon, pomegrante, rambutan, rose apple, sapodilla, black sapote, white sapote, soursop, spanish lime, starfruit, star apple, surinam cherry, sugar apple, tamarind, ugli fruit, and wax jambu at 0.5 ppm.

3. Lingonberries, juneberry, and salal at 5.0 ppm.

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. This notice includes a summary of the petition prepared by BASF Corporation, P.O. Box 13528, Research Triangle Park, North Carolina.

A. Residue Chemistry

1. *Plant metabolism*. The qualitative nature of the residues in plants and animals is adequately understood for the purposes of registration.

2. *Analytical method*. Analytical methods for detecting levels of sethoxydim and its metabolites in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances were submitted to EPA. The proposed analytical method involves extraction, partition, and clean-up. Samples are then analyzed by gas chromatography with sulfur-specific flame photometric detection. The limit of quantitation (LOQ) is 0.05 ppm.

B. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the reliability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by sethoxydim are discussed in Unit II. A. of the final rule on sethoxydim pesticide tolerances published in the **Federal Register** of October 8, 1998 (63 FR 54066) (FRL–6034–1)

1. *Animal metabolism*. In a rat metabolism study, excretion was extremely rapid and tissue accumulation was negligible.

2. *Metabolite toxicology*. As a condition to registration, BASF had been asked to submit additional toxicology studies for the hydroxy-metabolites of sethoxydim. EPA agreed with BASF's recommendation to use the most abundant metabolite, 5–OH–MSO2, as surrogate for all metabolites. Based on these data, it was concluded that the toxicological potency of the plant hydroxy-metabolites is likely to be equal or less than that of the parent compound. The tolerance expression for sethoxydim and its metabolites containing the 2-cyclohexen-1-one moiety, measured as parent. Hence, the hyrdroxy-metabolites are figured into all tolerance calculations.

3. *Endocrine disruption*. No specific tests have been performed with sethoxydim to determine whether the chemical may have an effect in humans that is similar to an effect produced by naturally-occurring estrogen or other endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. For purposes of assessing the potential dietary exposure, BASF has estimated aggregate exposure based on the Theoretical Maximum Residue Contribution (TMRC) from existing and pending tolerances for sethoxydim. (The TMRC is a ''worst case'' estimate of dietary exposure since it is assumed that 100% of all crops for which tolerances are established are treated and that pesticide residues are at the tolerance levels.) The TMRC from existing tolerances for the overall U.S. population is estimated at approximately 44% of the reference dose (RfD). BASF estimates indicate that dietary exposure will not exceed the RfD for any population subgroup for which EPA has data. This exposure assessment relies on very conservative assumptions 100% of crops will contain sethoxydim residues and those residues would be at the level of the tolerance which results in an overestimate of human exposure.

Other potential sources of exposure of the general population to residues of pesticides are residues in drinking water and exposure from non-occupational sources.

ii. *Drinking water*. Based on the available studies submitted to EPA for assessment of environmental risk, BASF does not anticipate exposure to residues of sethoxydim in drinking water. There is no established maximum concentration level (MCL) for residues of sethoxydim in drinking water under the safe drinking water act (SDWA).

2. *Non-dietary exposure*. BASF has not estimated non-occupational exposure for sethoxydim. Sethoxydim is labeled for use by homeowners on and around the following use sites: Flowers, evergreens, shrubs, trees, fruits, vegetables, ornamental groundcovers, and bedding plants. Hence, the potential for non-occupational exposure to the general population exists. However, these use sites do not appreciably increase exposure. Protective clothing requirements, including the use of gloves, adequately protect homeowners when applying the product. The product may only be applied through hose-end sprayers or tank sprayers as a 0.14% solution. Sethoxydim is not a volatile compound so inhalation exposure during and after application would be negligible. Dermal exposure would be minimal in light of the protective clothing and the low application rate. According to BASF, post-treatment (re-entry) exposure would be negligible for these use sites as contact with treated surfaces would be low. BASF concludes that the potential for non-occupational exposure to the general population is insignificant.

D. Cumulative Effects

BASF also considered the potential for cumulative effects of sethoxydim and other substances that have a common mechanism of toxicity. BASF is aware of one other active ingredient which is structurally similar, clethodim. However BASF believes that consideration of a common mechanism of toxicity is not appropriate at this time. BASF does not have any reliable information to indicate that toxic effects produced by sethoxydim would be cumulative with clethodim or any other chemical; thus BASF is considering only the potential risks of sethoxydim in its exposure assessment.

E. Safety Determination

1. *U.S. population*. RFD using the conservative exposure assumptions described above, BASF has estimated that aggregate exposure to sethoxydim

will utilize 44% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD. Therefore, based on the completeness and reliability of the toxicity data, and the conservative exposure assessment, BASF concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of sethoxydim, including all anticipated dietary exposure and all other non-occupational exposures.

2. *Infants and children*—i. Developmental toxicity was observed in a developmental toxicity study using rats but was not seen in a developmental toxicity study using rabbits. In the developmental toxicity study in rats a maternal no observed adverse effect level (NOAEL) of 180 milligrams/kilograms/day (mg/kg/day) and a maternal lowest observed adverse effect level (LOAEL) of 650 mg/kg/day (irregular gait, decreased activity, excessive salivation, and anogenital staining) was determined. A developmental NOAEL of 180 mg/kg/day and a developmental lowest effect level (LEL)__ of 650 mg/kg/day (21 to 22% decrease in fetal weights, filamentous tail and lack of tail due to the absence of sacral and/or caudal vertebrae, and delayed ossification in the hyoids, vertebral centrum and/or transverse processes, sternebrae and/or metatarsals, and pubes). Since developmental effects were observed only at doses where maternal toxicity was noted, the developmental effects observed are believed to be secondary effects resulting from maternal stress.

ii. *Reproductive toxicity*. A 2–generation reproduction study with rats fed diets containing 0, 150, 600, and 3,000 ppm (approximately 0, 7.5, 30, and 150 mg/kg/day) produced no reproductive effects during the course of the study. Although the dose levels were insufficient to elicit a toxic response, the Agency has considered this study usable for regulatory purposes and has established a free-standing NOAEL of 3,000 ppm (approximately 150 mg/kg/day), Proposed Rule of March 15, 1995, (60 FR 13941) (FRL–4936–1)

iii. *Reference dose*. Based on the demonstrated lack of significant developmental or reproductive toxicity BASF believes that the RfD used to assess safety to children should be the same as that for the general population, 0.09 mg/kg/day. Using the conservative exposure assumptions described above, BASF has concluded that the most sensitive child population is that of children ages 1 to 6. BASF calculates the exposure to this group to be approximately 96% of the RfD for all uses (including those proposed in this document). Based on the completeness and reliability of the toxicity data and the conservative exposure assessment, BASF concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the residues of sethoxydim, including all anticipated dietary exposure and all other non-occupational exposures.

F. International Tolerances

A maximum residue level has not been established by the Codex Alimentarius Commission for residues of sethoxydim on the crops included in this proposal.

[FR Doc. 02–19983 Filed 8–6–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–2139; FRL–7186–5]

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 ID number OPP–2002–2139, must be received on or before September 6, 2002.

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 ID number OPP–2002–2139 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6224; e-mail address: miller.joanne@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/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–2139. 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