

teleconference on the SAB Website ([www.epa.gov/sab](http://www.epa.gov/sab)) under the DRAFT REPORTS subheading. Please contact Ms. Rhonda Fortson (see below) for details on the availability of this Letter Report.

**FOR FURTHER INFORMATION CONTACT:**

Members of the public desiring additional information about the meeting, must contact Mr. Robert Flaak, Designated Federal Officer, Clean Air Scientific Advisory Committee, EPA Science Advisory Board (1400A), Suite 6450, U.S. EPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone/voice mail at (202) 564-4546; fax at (202) 501-0582; or via e-mail at [flaak.robert@epa.gov](mailto:flaak.robert@epa.gov). A copy of the draft agenda will be posted on the SAB Website ([www.epa.gov/sab](http://www.epa.gov/sab)) (under the AGENDAS subheading) approximately 12 days before the meeting.

Members of the public desiring additional information about the meeting location or the call-in number, must contact Ms. Rhonda Fortson, Management Assistant, Clean Air Scientific Advisory Committee, EPA Science Advisory Board (1400A), Suite 6450, U.S. EPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone/voice mail at (202) 564-4563; fax at (202) 501-0582; or via e-mail at [fortson.rhonda@epa.gov](mailto:fortson.rhonda@epa.gov).

**Written Comments**—In accordance with the Federal Advisory Committee Act (FACA), the public is encouraged to submit written comments on these two draft reports. Written comments must be received no later than the day prior to the meeting, preferably in electronic format (e-mail). Comments received after the meeting will be forwarded to the Committee, but will not be available for comment or discussion during the meeting. **Oral Comments**—The SAB will have a brief period (no more than 30 minutes) available during the Teleconference meeting for applicable public comment. Members of the public who wish to make a brief oral presentation must contact Mr. Flaak in writing (by letter or by fax—see previously stated information) no later than 12 noon Eastern Time, Thursday, February 21, 2002 in order to be included on the Agenda. The oral public comment period will be limited to thirty minutes divided among the speakers who register. Registration is on a first come basis, allowing approximately three to five minutes per speaker or organization. Speakers who are unable to register in time, may provide their comments in writing.

**Providing Oral or Written Comments at SAB Meetings**

It is the policy of the Science Advisory Board to accept written public comments of any length, and to accommodate oral public comments whenever possible. The Science Advisory Board expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements.

**Oral Comments:** In general, each individual or group requesting an oral presentation at a face-to-face meeting will be limited to a total time of ten minutes. For conference call meetings, opportunities for oral comment will usually be limited to no more than three minutes per speaker and no more than fifteen minutes total, unless otherwise stated. Deadlines for getting on the public speaker list for a meeting are given above. Speakers should bring at least 35 copies of their comments and presentation slides for distribution to the reviewers and public at the meeting.

**Written Comments:** Although the SAB accepts written comments until two days following the date of the meeting (unless otherwise stated above), written comments should be received in the SAB Staff Office at least one week prior to the meeting date so that the comments may be made available to the committee for their consideration. Comments should be supplied to the appropriate DFO at the address/contact information noted above in the following formats: one hard copy with original signature, and one electronic copy via e-mail (acceptable file formats: WordPerfect, Word, or Rich Text files (in IBM-PC/Windows 95/98 format). Those providing written comments and who attend the meeting are also asked to bring 35 copies of their comments for public distribution.

**General Information**—Additional information concerning the EPA Science Advisory Board, its structure, function, and composition, may be found on our Website (<http://www.epa.gov/sab>) and in the just-released *EPA Science Advisory Board FY2001 Annual Staff Report—Expanding Expertise and Experience* which is available from the SAB Publications Staff at (202) 564-4533 or via fax at (202) 501-0256. Committee rosters, draft Agendas and meeting calendars are also located on our website.

**Meeting Access**—Individuals requiring special accommodation at this meeting, including wheelchair access to the conference room, should contact Mr. Flaak at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: February 4, 2002.

**Donald G. Barnes,**

*Staff Director, Science Advisory Board.*

[FR Doc. 02-3095 Filed 2-7-02; 8:45 am]

**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

[PF-1065; FRL-6819-4]

**Notice of Filing 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-1065, must be received on or before March 11, 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 control number PF-1065 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](mailto: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" 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-1065. 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-1065 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](mailto: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-1065. 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 pesticide petitions 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 the petitions contain 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 petitions. Additional data may be needed before EPA rules on the petitions.

**List of Subjects**

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

Dated: January 26, 2002.  
**Peter Caulkins, Acting,**  
*Director, Registration Division, Office of Pesticide Programs.*

**Summaries of Petitions**

The petitioner's summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the BASF Corporation, the registrant, and represents the view of BASF Corporation. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summaries 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 4**

##### *PP OE6068 and 1E6226*

EPA has received pesticide petitions (OE6068 and 1E6226) from the Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #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 180.494 by establishing tolerances for residues of pyridaben, (2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyridazin-3(2H)-1) as specified in 40 CFR 180.494 in or on the raw agricultural commodities:

1. PP OE6068 proposes the establishment of a tolerance in or on strawberry at 2.5 parts per million (ppm).

2. PP 1E6226 proposes the establishment of a tolerance in or on hops at 10 ppm.

EPA has determined that the petitions contain 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 petitions. Additional data may be needed before EPA rules on the petitions.

#### *A. Residue Chemistry*

1. *Plant and animal metabolism.* The nature of the residue in plants is adequately understood. The residue of concern is pyridaben *per se* as specified in 40 CFR 180.494. The nature of the residue in animals is adequately understood. The residue of concern is pyridaben and its metabolites PB-7 (2-tert-butyl-5-[4-(1-carboxy-1-methylethyl)benzylthio]-4-chloropyridazin-3(2H)-1) and PB-9 (2-tert-butyl-4-chloro-5-[4-(1,1-dimethyl-2-hydroxyethyl)benzylthio]-chloropyridazin-3(2H)-1) as specified in 40 CFR 180.494.

2. *Analytical method.* The proposed analytical method involves extraction, partition, clean-up, and detection of residues by gas chromatography/electron capture detector (GC/ECD).

3. *Magnitude of residues.* Strawberry residue trials were conducted according to a split application program depending upon location for a total of 10 trials in 6 states. Residues of pyridaben were measured by GC/ECD. The method of detection (MOD) had a limit of detection (LOD) of 0.05 ppm. Residues ranged from 0.19 to 2.26 ppm for 1 application program and 0.325 to 1.28 ppm for the second application program.

Three hop residue trials were conducted, one in each of three states. Residues of pyridaben were measured by GC/ECD. The MOD had a LOD of 0.05 ppm. Residues ranged from 4.35 to 8.49 ppm.

#### *B. Toxicological Profile*

1. *Acute toxicity—i. Subpopulation females 13+ years old.* No observe adverse effect level (NOAEL) = 13 milligrams/kilograms (mg/kg). In a developmental toxicity study, Sprague-Dawley rats (22/group) from Charles River, United Kingdom, received NC-129 (Pyridaben, 98.0% active ingredient via gavage at dose levels of 0, 2.5, 5.7, 13.0, or 30.0 mg/kg/day from gestation day 6 through 15, inclusive. Natural mating was used. Maternal toxicity, observed at 13.0 and 30.0 mg/kg/day, consisted of decreased body weight/weight gain and food consumption during the dosing period. Based on these effects, the maternal toxicity lowest observe adverse effect level (LOAEL) is 13.0 mg/kg/day and the maternal toxicity NOAEL is 4.7 mg/kg/day (82% of 5.7 mg/kg/day based on concentration analysis). Developmental toxicity NOAEL is 13.0 mg/kg/day based on observed decreased fetal body weight and increased incomplete ossification in selected bones at 30.0 mg/kg/day LOAEL. With the 100 uncertainty factor (UF) (10X for interspecies extrapolation and 10X for intraspecies variability) the acute reference dose (RfD) for females 13+ is 0.13 mg/kg/day.

ii. *General population including infants and children.* NOAEL = 50 mg/kg. In an acute neurotoxicity study, CD rats (10/sex/group) were administered a single oral dose (gavage) of NC-129 in 1% aqueous carboxymethyl cellulose of 0 (vehicle), 50, 100, and 200 mg/kg active ingredient equivalents: 44.3, 79.6, and 190.0 mg/kg for males and 44.5, 99.7, and 190.0 mg/kg body weight for females. The animals were observed for mortality and clinical signs of toxicity for 14 days post-dosing. During the first 5 days, compound-related decreases in body weight gain were noted in mid-dose males (17%), and females (36%), and high-dose males (74%); the high-dose females lost weight (4 g) during the first 4 days of the observation period. Food consumption was low in all treated groups on the day of dosing with severe effect seen in the high-dose males (73% lower than controls). Dose-dependent increases in clinical signs (piloerection, hypoactivity, tremors, and partially closed eyes) were seen in mid-dose males, and high-dose males, and females. These effects were reversible by observation day 4. Treatment-related findings in the functional observational

battery consisted of lower body temperature and reduced motor activity among the high-dose males. No treatment-related gross or microscopic neuropathologic findings were present. The NOAEL for systemic toxicity is 50 mg/kg for both sexes. The LOAEL of 100 mg/kg/day is based on systemic toxicity including clinical signs and decreased food consumption and body weight gain. With the 100 UF (10X for interspecies extrapolation and 10X for intraspecies variability) the acute RfD for the general population is calculated to be 0.5 mg/kg/day.

2. *Short-term and intermediate-term toxicity.* NOAEL = 100 mg/kg/day. In a 21-day dermal toxicity study, repeated doses of pyridaben were applied topically to approximately 10% of the body surface area of rats at doses of 0, 30, 100, 300, or 1,000 mg/kg/day for 21 days. Increased squamous cell hyperplasia and/or surface accumulation of desquamated epithelial cells were noted sporadically in the 100, 300, and 1,000 mg/kg/day dose groups. These findings appear to be due to abrasions of the skin when the powdered substance was applied onto the skin, rather than a dose-related effect. No gross dermal irritation effects were noted. Based on the results of the study, the systemic dermal toxicity NOAEL is 100 mg/kg/day. The systemic dermal toxicity LOAEL is determined to be 300 mg/kg/day based on decreased body weight in the females. The dermal irritation NOAEL is 100 mg/kg/day. (Note: In agreement, a dermal equivalent dose of 94 mg/kg/day is derived if the maternal oral NOAEL of 4.7 mg/kg/day (based on decreased body weight/weight gain and food consumption) in the four rat oral developmental toxicity study is adjusted by the proposed 5% dermal absorption rate).

3. *Chronic toxicity.* EPA has established the RfD for pyridaben at 0.005 mg/kg/day. This RfD is based on a 1-year feeding study in dogs with a NOAEL of 0.5 mg/kg/day and an UF of 100 based on decreased body weight, emesis, and ptalism.

4. *Carcinogenicity.* Because pyridaben has been classified by EPA as a Group E chemical (no evidence of carcinogenicity to humans), no additional analysis is necessary regarding carcinogenicity of this chemical.

#### *C. Aggregate Exposure*

1. *Dietary exposure—i. Food.* From the acute dietary (food only) risk assessment, the calculated exposure yields dietary (food only) percentage of the acute RfD for females 13+ years old nursing is 14%. The highest calculated

exposure yields dietary (food only) percentage of the acute RfD for the remainder of the population is 19% for infants <1-year old. This risk estimate should be viewed as highly conservative as tolerance level residues and 100% crop use was used. Refinement using anticipated residue values and percent crop treated data in conjunction with a Monte Carlo analysis will result in a lower acute dietary exposure estimate.

In conducting a Tier 2 chronic dietary risk assessment, EPA has made somewhat conservative assumptions in that 100% of crops treated with anticipated residues will contain pyridaben residues. The chronic dietary exposure evaluation model (DEEM) analysis indicates that the most highly exposed population subgroup is non-nursing infants which occupy up to 64% of the chronic population adjusted dose (PAD).

ii. *From drinking water.* Based on information currently available to EPA, pyridaben is immobile and thus unlikely to leach to ground water. There is no established maximum contaminant level goal (MCLG) for residues of pyridaben in drinking water. No health advisory levels (HALs) for pyridaben in drinking water have been established. EPA uses the generic expected environmental concentration (GENEEC) and screening concentration in ground water (SCI-GROW) screening models to estimate surface and ground water concentrations for first-Tier exposure assessments. As screening models designed to estimate the concentrations found in surface and ground water for use in ecological risk assessment, they provide upper-bound values on the concentrations that might be found in ecologically sensitive environments because of the use of a pesticide. The models predict that as much as 2.3 parts per billion (ppb) and 0.0003 ppb of pyridaben may be found in surface and ground water, respectively. The modeling data were compared to the results from modeling equations used to calculate the acute and chronic drinking water level of concern (DWLOC) for pyridaben in surface and ground water.

a. *Acute exposure and risk.* Acute DWLOC have been calculated by EPA at the following amounts: U.S. population—14,000 g/Liter g/(L); adult male 20+ years old—15,000 g/L; adult female 13+, pregnant, non-nursing—2,200 g/L; infant <1, nursing—1,100 g/L.

b. *Chronic exposure and risk.* Chronic DWLOC have been calculated by EPA at the following amounts: U.S. population—140 g/L; adult male, 13–19 years old—160 g/L; adult female 13+,

nursing—100 g/L; infant <1, non-nursing—7 g/L.

2. *From non-dietary exposure.* Pyridaben is currently not registered for use on residential non-food sites. Thus, a residential exposure assessment is not required. There is a potential for occupational exposure to pyridaben during, mixing, loading, and application activities. However, risks from these routes of exposure are considered negligible.

#### D. Cumulative Effects

EPA does not have, at this time, available data to determine whether pyridaben 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, pyridaben does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, BASF Corporation has not assumed that pyridaben has a common mechanism of toxicity with other substances.

#### E. Safety Determination

1. *U.S. population—i. Acute risk.* Using the published and pending tolerances, the dietary (food only) percentage of the acute RfD maximum is only 19% for nursing infants <1-year old. This risk estimate should be viewed as highly conservative; refinement using additional anticipated residues values and percent crop treated data in conjunction with Monte Carlo analysis will result in a lower acute dietary exposure estimate. The acute dietary exposure does not exceed EPA's level of concern. Pyridaben is immobile and thus unlikely to leach to ground water. The modeling data for pyridaben in drinking water indicate levels less than EPA's DWLOC for acute exposure. Since a refined acute risk for food only would not exceed EPA's levels of concern for acute dietary exposures and the monitoring and modeling levels in water are less than the acute DWLOC, BASF Corporation does not expect aggregate acute exposure to pyridaben will pose an unacceptable risk to human health.

ii. *Chronic risk.* Using the somewhat conservative anticipated residue contribution (ARC) exposure assumptions described in Unit III.B., EPA has concluded that aggregate exposure to pyridaben from food will utilize 20% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is discussed below. EPA

generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The residues of pyridaben in drinking water do not exceed EPA's DWLOC. Pyridaben does not have any residential uses. BASF Corporation does not expect the aggregate exposure to exceed 100% of the RfD.

iii. *Short-term and intermediate-term risk.* Aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential uses. Since there are no residential uses, a short-term or intermediate-term aggregate risk assessment is not required.

iv. *Aggregate cancer risk for U.S. population.* Since pyridaben has been classified as a Group E chemical (no evidence of carcinogenicity to humans), a cancer risk assessment is not required.

v. *Endocrine disrupter effects.* EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. . . ." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry, and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of the Food Quality Protection Act (FQPA) (Public Law 104–170) (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

vi. *Determination of safety.* Based on these risk assessments, BASF Corporation concludes that there is a reasonable certainty that no harm will result from aggregate exposure to pyridaben residues.

2. *Infants and children—i. Safety factor for infants and children in assessing the potential for additional sensitivity of infants and children to residues of pyridaben.* 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 prenatal and postnatal effects from exposure to

pyridaben, 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 MOE and uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional ten-fold margin of exposure/uncertainty factor 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 margin of exposure/safety factor MOE/(SF).

*ii. Developmental toxicity studies—a. Rats.* In a developmental toxicity study in rats, the maternal (systemic) NOAEL was 4.7 mg/kg/day. The maternal LOAEL of 13 mg/kg/day was based on decreases in body weight, body weight gain, and food consumption during the dosing period (GD 6–15). The developmental (fetal) NOAEL was 13 mg/kg/day. The developmental LOAEL of 30 mg/kg/day was based on decreased fetal body weight and increased incomplete ossification in selected bones.

*b. Rabbits.* In an oral developmental toxicity study in rabbits, the maternal (systemic) NOAEL was not established. The maternal LOAEL of 1.5 mg/kg/day was based on decreases in body weight gain and food consumption. There was no developmental toxicity observed at any dose tested. Therefore, the developmental (fetal) NOAEL is 15 mg/kg/day at the highest dose tested (HDT).

*iii. Reproductive toxicity study—rats.* In the 2-generation reproductive toxicity study in rats, the parental (systemic) NOAEL was 2.3 mg/kg/day. The parental (systemic) LOAEL of 7 mg/kg/day was based on decreased body weight, decreased body weight gains, and decreased food efficiency. The reproductive (pup) NOAEL was 7 mg/kg/day and the LOAEL was 7 mg/kg/day at the HDT.

*iv. Prenatal and postnatal sensitivity.* The toxicological data base for evaluating prenatal and postnatal toxicity for pyridaben is complete with respect to current data requirements. There are no prenatal or postnatal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies as well as the 2-generation rat reproductive toxicity study. Based on the above, BASF Corporation has concluded that reliable data support removing the additional 10X SF for protection of infants and children.

*v. Conclusion.* There is a complete toxicity data base for pyridaben and exposure data are complete or estimated based on data that reasonably account for potential exposures.

*a. Acute risk.* Using the somewhat conservative exposure assumptions described above, the percentage of the acute RfD that will be utilized by dietary (food) exposure to residues of pyridaben maximize to 19% for nursing infants <1-year old. The acute DWLOC does not exceed EPA's level of concern. Taking into account the completeness and reliability of the toxicity data and this conservative exposure assessment, BASF Corporation concludes that there is a reasonable certainty that no harm will result to infants and children from acute aggregate exposure to pyridaben residues.

*b. Chronic risk.* Using the somewhat conservative exposure assumptions described above, EPA has calculated that the percentage of the RfD that will be utilized by dietary (food) exposure to residues of pyridaben maximizes at 64% of the chronic PAD for the most highly exposed population subgroup, non-nursing infants. The chronic DWLOC does not exceed EPA's level of concern. There are no residential uses for pyridaben.

Taking into account the completeness and reliability of the toxicity data and this conservative exposure assessment, BASF Corporation concludes that there is a reasonable certainty that no harm will result to infants and children from chronic aggregate exposure to pyridaben residues.

*c. Short-term or intermediate-term risk.* Aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential uses. Since the chronic food and chronic DWLOC do not exceed EPA's level of concern and there are currently no indoor or outdoor residential uses of pyridaben, the short-term and intermediate-term aggregate risk does not exceed EPA's level of concern.

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

#### F. International Tolerances

There are no CODEX, Canadian, or Mexican maximum residue levels established for pyridaben on hops or strawberry.

[FR Doc. 02-2986 Filed 2-7-02; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[PF-1067; FRL-6821-2]

### Notice of Filing Pesticide Petitions to Establish Tolerances for Certain Pesticide Chemicals 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 certain pesticide chemicals in or on various food commodities.

**DATES:** Comments, identified by docket control number PF-1067, must be received on or before March 11, 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 control number PF-1067, in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-3194; e-mail address: brothers.shaja@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: