

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 is reopening the comment period for an additional 30 days and will continue to make available for comment an options paper on exclusive use and data compensation rights for data submitted to the Agency in support of tolerance and tolerance exemption actions. As part of the Food Quality Protection Act of 1996, Congress amended section 408(i) of the FFDCA addressing such rights. The Agency is currently evaluating how to implement this new provision and is seeking public comment. The options paper briefly discusses the new section 408(i) of the FFDCA and the Agency's practices regarding data compensation and exclusive use; the current compensation and exclusive use process the Agency implements under section 3 of FIFRA; and presents three options for implementing the new provision. The options represent different interpretations focusing on who the data submitters may be. However, the Agency also seeks comments on other interpretations of section 408(i) and suggested procedures for implementing whatever option the commenter prefers.

EPA will consider the comments received and develop a detailed proposal for implementing data rights under section 408(i) of FFDCA.

**List of Subjects**

Environmental protection, Pesticide tolerances, Data compensation.

Dated: April 4, 2000.

**Marcia E. Mulkey**,  
 Director, Office of Pesticide Programs.  
 [FR Doc. 00-9097 Filed 4-11-00; 8:45 am]  
**BILLING CODE 6560-50-F**

**ENVIRONMENTAL PROTECTION AGENCY**

[PF-934; FRL-6551-8]

**Notice of Filing a Pesticide Petition to Establish a Tolerance for Certain Pesticide Chemicals in or on Food**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the amendment 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-934, must be received on or before May 12, 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-934 in the subject line on the first page of your response.  
**FOR FURTHER INFORMATION CONTACT:** By mail: Mary Waller, fungicide Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-9354; e-mail address: waller.mary@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:

Cat-egories	NAICS codes	Examples of poten-tially affected entities
Industry	111	Crop production

Cat-egories	NAICS codes	Examples of poten-tially affected entities
	112 311 32532	Animal production Food manufacturing Pesticide manufac-turing

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-934. 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-934 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, Ariel Rios Bldg., 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-934. 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: April 5, 2000.

**James Jones,**

*Director, Registration Division, Office of Pesticide Programs.*

### **Summary of Petition**

The petitioner summary of the amendment to a 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.

### **American Cyanamid Company**

*PP 7F4816*

EPA has received an amendment to pesticide petition (7F4816) from American Cyanamid Company, Global Agricultural Products Research Division, P.O. Box 400, Princeton, NJ 08543-0400 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of dimethomorph (E,Z)4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]-morpholine in or on the raw agricultural commodity (RAC) imported grapes at 3.5 parts per million (ppm) and in or on imported grape, raisin, at 6 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.

#### *A. Residue Chemistry*

1. *Plant metabolism.* Radiolabeled dimethomorph was applied to grape vines at 0.8 lb. active ingredient per acre (ai/acre) for 4 consecutive weeks, giving a total application rate of 3.2 lb. ai/acre. The amount of total radioactive residue (TRR) in or on grapes harvested 35 days following the last of these applications was 14.6 ppm. Parent dimethomorph accounted for 87.3% of the TRR (12.7 ppm). No metabolites were identified that require regulation.

2. *Analytical method.* FAMS 002-04 is a reliable high performance liquid chromatography (HPLC) method for the determination of dimethomorph residues in grape and raisin.

3. *Magnitude of residues.* The residue data were collected from studies having multiple applications (3-11) of dimethomorph with a maximum seasonal rate of up to 2.94 lb. ai/acre. The resulting dimethomorph residues in the RAC grape ranged from < 0.01 ppm (the limit of quantitation (LOQ) of the

method) to 2.55 ppm. Residues of dimethomorph upon processing of grape to raisin were concentrated by a factor of 1.8x. Residues of dimethomorph did not concentrate upon processing of grape to juice or wine. Therefore, tolerances of 3.5 ppm in/on imported grape and 6.0 ppm in/on imported raisins are proposed.

#### B. Toxicological Profile

The toxicity of dimethomorph has been studied extensively and there is a complete data base to address the acute and chronic effects, effects on genetic material, the potential for carcinogenicity, or teratogenicity, and effects on reproductive performance or growth of offspring. EPA has previously evaluated the available toxicological data and considered its 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 variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The toxicological profile for dimethomorph which supports this petition for tolerances of dimethomorph in or on imported grapes and imported raisins was previously published in the **Federal Register** final rule of October 13, 1998 (63 FR 545587) (FRL-6036-7).

#### C. Aggregate Exposure

1. *Dietary exposure.* To assess the potential chronic dietary exposure to dimethomorph residues for all tolerances in effect early in 1999, EPA used the dietary exposure evaluation model (DEEM 89) to conduct a chronic dietary (food only) exposure analysis. In conducting this analysis, EPA made very conservative assumptions: that all commodities having dimethomorph tolerances contain residues of dimethomorph and those residues are at the level of the tolerance. These assumptions result in an overestimate of human dietary exposure. All section 18 tolerances (cantaloupes, watermelons, cucumbers, squash, and tomatoes) were included in this assessment along with tolerances for cereal grains crops, and potatoes. The results of the analysis were theoretical maximum residue contributions (TMRC) that were equivalent to the following percentages of the population adjusted dose (PAD) (equivalent to the reference dose (RfD), as EPA removed the extra 10x safety factor): U.S. population (total), 2%; nursing infants, 0.6%; non-nursing infants, 2.4%; children 1-6 years, 4.3%; and children 7-12 years, 3%. In a similar analysis utilizing data derived

by TAS, Inc., the chronic dietary exposure to dimethomorph was evaluated for tolerances pending at that time for imported commodities of hops, tomato, and grape (at 2 ppm with no tolerance for raisin proposed). The assumptions made in this assessment were likewise very conservative: all of these commodities (domestically-produced and imported) contain residues of dimethomorph and residues at the level of the tolerance. The results of the analyses were TMRC values that were equivalent to the following percentages of the PAD: U.S. population (total), 1.58%; all infants, 2.38%; non-nursing infants, 2.6%; children 1-6 years, 4.39%; and children 7-12 years, 1.81%. From these two analyses, American Cyanamid had previously concluded that the chronic dietary exposure to dimethomorph from all established and pending tolerances was less than 10% of the PAD for the U.S. population and for population subgroups (e.g., for children 1-6 years, 4.3% plus 4.39%). This conclusion was supported by conservative assumptions and the expiration of the section 18 tolerances for tomato commodities. Given these factors, an increase of the proposed tolerance for imported grape from 2 ppm to 3.5 ppm and the addition of a 6 ppm tolerance for raisin is not expected to exceed the allowed chronic dietary exposures.

i. *Food—acute dietary exposure.* An acute dietary risk assessment is not required because no acute toxicological endpoints were identified by EPA for dimethomorph.

ii. *Drinking water.* The tolerances proposed in this petition are for imported commodities, thus there is no direct impact of establishment of these tolerances on domestic drinking water. Currently, the only federally-registered food/feed use of dimethomorph in the United States is on potato crops. For this use, the drinking water level of concern (DWLC) from chronic exposure to dimethomorph was estimated by EPA to be 3,400 parts per billion (ppb) for the U.S. population and for males 13 years and older; 2,900 ppb for females 13 years and older; and 960 ppb for children (1-6 years of age). These levels are all much greater than that calculated from the generic estimated environmental concentration (GENEEC; 24 ppb for 56 days) which simulates the residues in surface water. Dimethomorph residues in ground water were also estimated using the screening concentration in ground water model, SCI-GRO, but these estimates were significantly lower than those obtained from the GENEEC model. Given the low levels of dimethomorph

residues as estimated by the GENEEC model and the large margin of exposure (40x-142x), the registered food use of dimethomorph does not meet or exceed a level of concern for residues in drinking water.

2. *Non-dietary exposure.* Currently, there are no registered residential uses for dimethomorph in the United States. Thus, an assessment of non-dietary exposure is not relevant to this petition.

#### D. Cumulative Effects

There is no information to indicate that any toxic effects produced by dimethomorph would be cumulative with those of any other chemical. The fungicidal mode of action of dimethomorph is unique; dimethomorph inhibits cell wall formation only in Oomycete fungi. The result is lysis of the cell wall which kills growing cells and inhibits spore formation in mature hyphae. This unique mode of action and limited pest spectrum suggest that there is little or no potential for cumulative toxic effects in mammals. In addition, the toxicity studies submitted to support this petition do not indicate that dimethomorph is a particularly toxic compound. No toxic end-points of potential concern were identified.

#### E. Safety Determination

1. *U.S. population.* The PAD is 0.1 milligram/kilogram bodyweight per day (mg/kg bwt/day), based on a no observed adverse effect level (NOAEL) of approximately 10 mg/kg bwt/day (200 ppm) from a 2-year dietary toxicity study in rats that demonstrated decreased body weight and liver foci in females at 750 ppm. The PAD is calculated using an uncertainty factor of 100. The combined TMRC for all current and pending dimethomorph tolerances will utilize less than 100% of the PAD for the general U.S. population. Since EPA generally has no concern for exposures below 100% of the PAD, EPA should conclude that there is a reasonable certainty that no harm will result from aggregate exposure to dimethomorph residues as result of establishment of the requested tolerances.

2. *Infants and children.* The results of the studies submitted to support this package provide no evidence that dimethomorph caused reproductive, developmental or fetotoxic effects. No such effects were noted at dose levels which were not maternally toxic. There is no evidence to indicate that children or infants would be more sensitive than adults to toxic effects caused by exposure to dimethomorph. The NOAELs observed in the developmental

and reproductive studies were 6 to 65 times higher than the NOAEL used to establish the PAD. Further, the combined TMRC values for all current and pending dimethomorph tolerances will utilize less than 100% of the PAD for each of these subgroups. Therefore, the registrant believes that the results of the toxicology and metabolism studies support both the safety of dimethomorph to humans based on the intended use as a fungicide on imported grapes and raisins and the granting of the requested tolerances

#### F. International Tolerances

There are no Codex tolerances established for dimethomorph.  
[FR Doc. 00-8959 Filed 4-11-00; 8:45 am]

BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

[PF-929; FRL-6498-8]

### Notice of Filing a Pesticide Petition to Establish a Tolerance 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-929, must be received on or before May 12, 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-929 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Indira Gairola, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-6379; e-mail address: gairola.indira@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:

Cat-egories	NAICS codes	Examples of poten-tially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufac-turing

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?

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2. *In person.* The Agency has established an official record for this action under docket control number PF-929. 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-929 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, Ariel Rios Bldg., 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-929. Electronic comments may also be filed online at many Federal Depository Libraries.

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