G. Effects on the Immune and Endocrine Systems

Platte has no information to suggest that 2,6–DIPN will adversely affect the immune or endocrine systems. The Agency is not requiring information on endocrine effects of this biochemical pesticide at this time.

H. Existing Tolerances/International Tolerances

No Codex maximum residue levels (MRLs) are established for residues of 2,6–DIPN in/on any food or feed crop.

[FR Doc 00–22166 Filed 8–29–00; 8:45 a.m.]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–967; FRL–6739–4]

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 a pesticide petition 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–967, must be received on or before September 24, 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–967 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, 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:

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–967. 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–967 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–967. 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 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 supports 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: August 21, 2000.

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 petitioners. 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.

9F05044, 9E06005, and 9E06057

EPA has received a pesticide petition 9F05044 from Novartis Crop Protection, 410 Swing Rd., Greensboro, NC 27419, proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of CGA–329351: (*R*)-2-[(2,6-dimethylphenyl) methoxyacetylamino] propionic acid methyl ester (also known as mefenoxam) in or on the food commodity rape seed (i.e., canola) at 0.05 parts per million (ppm). A Notice of Filing for Pesticide Petition 9F05044 was previously published in the **Federal Register** July 21, 2000 (65 FR 45375–45378) (FRL– 6593–5). This current Notice combines several petitions for the same pesticide, mefenoxam. In addition to PP 9F05044, EPA has also received a pesticide petition PP 9E06005 from Interregional Research Project (IR-4) Project Technology Centre of New Jersey, 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 part 180 by establishing tolerances for residues of CGA–329351: (*R*)-2-[(2,6-dimethylphenyl) methoxyacetylamino] propionic acid methyl ester in or on the food commodities herbs subgroup, fresh at 5.0 ppm; herbs subgroup, dried at 30 ppm; and fresh mint at 5.0 ppm. A second pesticide petition 9E06057 was received from IR–4 proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of CGA–329351: (*R*)-2-[(2,6-dimethylphenyl)-methoxyacetylamino]-propionic acid methyl ester in or on the food commodities kiwifruit at 0.05 ppm; atemoya, globe artichoke, starfruit, sugar apple, sweetsop, and true custard apple at 0.1 ppm; papaya, black sapote, caimito, canistel, mamey sapote, mango, and sapodilla at 0.3 ppm; and lingonberry at 1.0 ppm. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2) of FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petitions. Additional data may be needed before EPA rules on the petitions.

A. Residue Chemistry

1. *Plant metabolism*. Novartis believes the studies supporting these CGA–329351 petitions well characterize metabolism in plants and animals. The metabolism profile supports the use of an analytical enforcement method that accounts for combined residues of CGA–329351 and its metabolites, which contain the 2,6-dimethylaniline (DMA) moiety.

2. *Analytical method*. Novartis has submitted a practical analytical method involving extraction, filtration, acid reflux, steam distillation, and solid phase cleanup with analysis by confirmatory gas chromatography using Nitrogen/Phosphorous (N/P) detection. A total residue method is used for determination of the combined residues of CGA–329351 and its metabolites which contain the 2,6-dimethylaniline (DMA) moiety. The limit of quantitation (LOQ) for the method is 0.05 ppm.

3. *Magnitude of residues in plants*. The canola petition is supported by six field residue trials that were analyzed in concordance with the OPPTS guidelines based on expected reduced residues and environmental benefits of see applications. The six trials accounting for approximately 84% of commercial U.S. canola production (Agricultural Statistics, 1991), were conducted in Georgia (2%), Minnesota (16%), North Dakota (53%), South Dakota (2%), Idaho (6%), and Washington (5%). No residues (<0.05 ppm) of CGA–329351 were detected as 2,6-DMA in canola seed at either the 1x or 3x treatment rate. The IR-4 petitions are supported by 17 trials conducted in California and Florida.

4. *Magnitude of residue in animals.* As there were no detectable residues found with a 1x or 3x treatment regime, there is no expected impact on the dietary intake of livestock in association with this petition. Existing tolerances in 40 CFR part 180 are adequate to support the approval of this requested tolerance in the opinion of Novartis Crop Protection.

B. Toxicological Profile

1. *Acute toxicity*. The toxicological endpoints for CGA–329351 are discussed in Unit 4.B. of the **Federal Register** notice of July 25, 1997 (62 FR 40084) (FRL– 5726–4. The acute toxicity profile can be summarized as follows:

Rat acute oral study with a LD_{50} value of 490 mg/kg. Rat acute dermal study with a LD_{50} > 2,000 mg/kg. Rat inhalation study with a LC_{50} > 2.29 mg/liter (mL) air. Primary eye irritation

study in rabbit showing CGA–329351 as severely irritating. Primary dermal irritation study in rabbit showing CGA–329351 as slightly irritating. Skin sensitization studies in guinea pigs (Maximization and Buehler Test) showing CGA–329351 is not a sensitizer.

2. *Genotoxicty*. The toxicological endpoints for CGA–329351 are discussed in Unit 4.B. of the **Federal Register** notice of July 25, 1997 (62 FR 40084). The genotoxicity profile can be summarized as follows:

In vitro gene mutation test: Ames test - negative. *In vitro* chromosomal aberration test: Chinese hamster ovary - negative. *In vitro* gene mutation tests: Ames tests (3 independent studies) -negative; gene mutation in mouse lymphoma cells - negative; reverse mutation in Saccharomyces cerevisiae - negative. *In vitro* chromosomal aberration tests: Chinese hamster bone marrow cytogenetic test - negative. DNA repair study in rat hepatocytes - negative.

3. *Reproductive and developmental toxicity*. The toxicological endpoints for CGA–329351 are discussed in Unit 4.B. of the **Federal Register** notice of July 25, 1997 (62 FR 40084). The reproductive and developmental toxicity profile can be summarized as follows:

Teratology study in rats with a maternal no observed adverse effect level (NOAEL) of 10 milligrams/kilogram (mg/kg) based on reduced body weight gain. The fetuses remained entirely unaffected at the highest dose tested, (HDT) 250 mg/kg. Teratology study in rabbits with a maternal NOAEL of 150 mg/kg based on body weight loss. The developmental NOAEL was greater than or equal to the HDT, 300 mg/kg. 3–generation reproduction study in rats with a NOAEL of 1250 ppm, which was the HDT. The treatment had no effect on reproduction or fertility. Dominant lethal study in mouse - negative.

4. *Subchronic toxicity*. The toxicological endpoints for CGA–329351 are discussed in Unit 4.B. of the **Federal Register** notice of July 25, 1997 (62 FR 40084). The subchronic toxicity profile can be summarized as follows:

A 28-days cumulative toxicity study in rats with a NOAEL of 50 mg/kg based on liver changes. A 90–day subchronic dietary toxicity study in rats with a NOAEL of 250 ppm based on liver changes. A 90–day subchronic dietary toxicity study in dogs with a NOAEL of 250 ppm based on changes in blood biochemistry and hematology indicative of functional liver changes. A 21–day dermal toxicity study in rats with a NOAEL equal to or higher than the limit dose of 1,000 mg/kg. No local or systemic signs of toxicity were found. A 6–month dietary toxicity study in dogs with a NOAEL of 250 ppm based on changes in blood biochemistry indicative of hepatocellular damage.

5. *Chronic toxicity*. The toxicological endpoints for CGA–329351 are discussed in Unit 4.B. of the **Federal Register** notice of July 25, 1997 (62 FR 40084). The chronic toxicity profile can be summarized as follows:

A 24–month combined chronic toxicity/carcinogenicity study conducted in rats with a NOAEL of 250 ppm based on liver changes. No evidence of oncogenicity was seen. A 24–month oncogenicity study conducted in mice with a NOAEL of 250 ppm based on liver changes. No evidence of oncogenicity was seen.

6. *Animal metabolism*. The rat and goat rapidly metabolize and excrete via the same metabolic pathways as plants. Urinary metabolites are polar, primarily gucuronide and other conjugates. The parent compound is not retained in animal tissues nor secreted in milk.

7. *Metabolite toxicology*. Metabolites are considered to be of equal or less toxicity than the parent material.

8. *Endocrine disruption*. CGA–329351 does not belong to a class of chemicals known or suspected of having adverse effects on the endocrine system. Furthermore, supporting developmental toxicity studies in rats and rabbits, and a reproduction study in rats gave no indication of any effects on endocrine function related to development and reproduction. Subchronic and chronic treatment did not induce any morphological changes in endocrine organs and tissues.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. For the purposes of assessing the potential dietary exposure under the proposed tolerance, Novartis Crop Protection has estimated aggregate exposure from all crops for which tolerances are established or proposed (i.e., pesticide petitions 9F05044, 9E06005, and 9E06057).

ii. *Chronic exposure*. Under the conservative exposure assumption of residue levels being at tolerance level, less than 15% of the reference dose (RfD) will be utilized by the U.S. general population. EPA generally has no concern for exposures below 100% of the RfD. Therefore, based on the completeness and reliability of the toxicity data supporting these petitions, Novartis Crop Protection believes that there is a reasonable certainty that no harm will result from aggregate exposure to residues arising from this requested use, including anticipated dietary exposure and all other types of non–occupational exposures. From toxicity studies supporting the registration of CGA–329351, the active ingredient is classified as a Group ''E'' compound (evidence of noncarcinogenicity for humans). There was no evidence of carcinogenicity in a 24–month feeding trial in mice nor in a 24–month feeding study in rats at the dosage levels tested. The doses tested were adequate for identifying a cancer risk.

iii. *Acute exposure*. The risk from acute dietary exposure to CGA–329351 is considered to be very low. The NOAEL in a 28-day study was 50 mg/kg, which is 6-fold higher than the chronic NOAEL. Since chronic exposure assessment did not result in any unacceptable exposure for even the most impacted population subgroup, it is anticipated that also the acute exposure will be in an acceptable range. Calculations show that with the most exposed group (non–nursing infants) only 26% of the acute RfD will be utilized; the requested tolerance for rape seed (i.e., canola) does not add any measurable contribution to this exposure according to our analysis.

iv. *Drinking water*. Novartis Crop Protection anticipates the potential exposure from residues of drinking water to be insignificant due to the proposed seed treatment use pattern associated with this petition. The proposed IR–4 use patterns represent a negligible increase in terrestrial food crop application of mefenoxam. Although the potential for ground water contamination for current use patterns cannot be completely excluded where soils are highly permeable and the water table is shallow, the reduced use rate associated with CGA–329351 reduces potential ground water contamination relative to that for metalaxyl. Based on historical ground water monitoring data for metalaxyl from 5 states, levels typically do not exceed 3 ppb. This contamination level would lead to a potential uptake of 0.09 x10–3 mg/kg/day CGA–329351 (for an adult person consuming 2 liters of water per day), which is equivalent to 0.1% of the RfD. On the basis of this worst case estimate for CGA–329351, Novartis concludes that the contribution of any potential ground water contamination will be negligible.

2. *Non-dietary exposure*. CGA–329351 is registered for use as a product for use on turf and ornamentals for control of soil–borne diseases. However, the product is not used residentially by homeowners and the potential exposure to the general public from turf and ornamentals is thought to be negligible.

D. Cumulative Effects

Novartis Crop Protection believes that consideration of a common mechanism of toxicity is not appropriate at this time since there is no information to indicate that toxic effects produced by CGA–329351 would be cumulative with those of any other chemicals.

E. Safety Determination

1. *U.S. population*—i. *Acute risk*. The risk from acute dietary exposure to CGA–329351 is considered to be very low. The NOAEL in a 28-day study was 50 mg/kg, which is 6–fold higher than the chronic NOAEL. Since chronic exposure assessment did not result in any unacceptable exposure for even the most impacted population subgroup, it is anticipated that also the acute exposure will be in an acceptable range. Again, the requested tolerance on rape seed (i.e., canola) was found not to contribute any measurable additional impact on acute exposure to CGA–329351 so that for the general population less than 15% of the acute RfD is utilized.

ii. *Chronic risk*. Under the conservative exposure assumptions of residue levels being at tolerance level, less than 10% of the RfD will be utilized by the U.S. general population. Use on canola does not measurably contribute to this exposure, particularly given that no detectable residues were found even when 3x the use rate was utilized. Therefore, based on the completeness and reliability of the toxicity data supporting this petition, Novartis Crop Protection believes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of CGA–329351 taking into account dietary and non–occupational exposures.

2. *Infants and children*. There is no indication that CGA–329351 interferes with the pre–natal or neo–natal development, even when experimental animals were exposed to very high doses leading to maternal toxicity. Infants and children are not expected to show any particular sensitivity to CGA–329351.

i. *Acute risk*. The risk from acute dietary exposure to CGA–329351 is considered to be very low. The NOAEL in a 28–day study was 50 mg/kg, which is 6–fold higher than the chronic NOAEL. According to our analysis there is no measurable impact of the requested tolerance on the exposure to CGA–329351. The utilization of the acute RfD from the most exposed group is 26% (non–nursing infants).

ii. *Chronic risk*. Calculated on the basis of the TMRC for CGA–329351, utilization of RfD from dietary exposure of children is estimated as: 4.3% for nursing infants, 14% for non–nursing infants, 21% for 1 to 6 year old and 12% for children 7–12 years old.

F. International Tolerances

There are no Codex Maximum residue levels established for CGA–329351.

[FR Doc. 00–22011 Filed 8–29–00; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–965; FRL–6739–8]

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–965, must be received on or before September 29, 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–965 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Sharlene Matten, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 605–0514; e-mail address: matten.sharlene@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?

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2. *In person*. The Agency has established an official record for this action under docket control number PF–965. 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,