ENVIRONMENTAL PROTECTION AGENCY

[PF–1063; FRL–6814–1]

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–1063, must be received on or before January 22, 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–1063, in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9368; e-mail address: jamerson.hoyt@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–1063. 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–1063, 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–1063. 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: December 12, 2001.

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 BASF Corporation, Agricultural Products, 26Davis Drive, Research Triangle Park, NC 27709 and represents the view of BASF Corporation. 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 4

PP 0E6209

EPA has received a pesticide petition 0E6209 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 part 180 by establishing a tolerance for residues of (3,6-dichloro-o-anisic acid (dicamba) in or on the raw agricultural commodities (RAC): Corn, sweet, kernel plus cob with husks removed at 0.04 part per million (ppm); corn, sweet, forage at 0.50 ppm; and corn, sweet, stover at 0.50 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.* The metabolism is adequately understood on the basis of soybean, asparagus, cotton, sugarcane, and published data on grass. In the majority of registered crops, the major metabolite is the 3,6-dichloro-5-OH-o-anisic acid. Tolerances are expressed as the dicamba parent plus the respective major metabolite.

2. *Analytical method.* BASF Corp. has provided suitable independently validated analytical methods for detecting and measuring levels of dicamba, and its metabolites in or on food with a limit of detection that allows monitoring of food with residues at or above the levels described in these and the existing tolerances. Adequate methods are available in PAM-II for enforcement purposes. The analytical method involves extraction, partition, clean-up and detection of residues by gas chromatography/electron capture detector (gc/ecd).

3. *Magnitude of residues.* Residue trials have been conducted with dicamba/diflufenzopyr end-use product distinct on the sweet corn crop for expanded use requested in the subject petition. The tolerances listed below are based on the maximum expected residue from geographically representative field trial data: Proposed tolerances for combined residues of the herbicide dicamba (3,6-dichloro-o-anisic acid) and its metabolite 3,6-dichloro-5-hydroxy-o-anisic acid in or on the RAC as follows (40 CFR 180.227(a)): Corn, sweet, kernel plus cob with husks removed at 0.04 ppm; corn, sweet, forage at 0.05 ppm; and corn, sweet, stover at 0.05 ppm.

4. *Animal residue.* The uses proposed do not yield secondary residues in meat, and milk above the tolerances already published under 40 CFR 180.227. Data from metabolism and feeding studies in poultry have established that the maximum expected dietary burden from crops treated with dicamba, will not result in quantifiable residues above the limits of the analytical method.

B. Toxicological Profile

1. *Acute toxicity.* Oral rat LD_{50}: 1,879 milligrams/kilograms (mg/kg) (m) and 1,581 mg/kg (f). Acute dermal rat LD_{50}: > 2,000 kg/kg (m/f). Acute inhalation rat LC_{50}: > 9.6 mg/L (m/f). Primary eye irritation: Extremely irritating and corrosive to the eye. Primary dermal irritation rabbits: Not a primary skin irritant. Dermal sensitization guinea pigs: Moderate potential to cause dermal sensitization. Acute neurotoxicity: No observed adverse levels (NOAEL) < 300 mg/kg (low dose). No neuropathological effects were found.

2. *Genotoxicity.* Ames: Negative. *In vitro* chromosome aberration in Chinese Hamster Ovary: Negative. Sex-linked recessive lethal in Drosophila: Negative. Aberrations in rat bone marrow: Negative. Mitotic recombination: Negative. UDH Unscheduled DNA synthesis (UDS) with WI-38) human lung fibroblasts: Negative. Differential toxicity with *E. coli* pol *A and B. subtillus:* Positive. Differential toxicity with *S. typhimurium*: Negative. UDS in human lung lymphocytes with activation: Negative; slight increase of sister chromatid exchange in human cultured lymphocytes; positive in *in vivo* unwinding of liver DNA Inhalable Particles (in ip) injected rats.

3. *Reproductive and developmental toxicity.* Rodent developmental toxicity rat: Oral doses of 0, 64, 160, or 400 mg/kg were administered daily during gestation days 6 to 19. The numbers of implantations, resorptions, and fetuses for test animals were similar to those numbers for control animals. No abnormalities were attributed to exposure to dicamba. Technical dicamba was not found to be teratogenic with the test system/study design employed. Maternal toxicity was found only at the highest dose tested (HDT) and the NOAEL was 160 mg/kg/day.

i. *Rabbit developmental toxicity.* Dicamba was administered orally (undiluted) via capsule to groups of 20 artificially inseminated New Zealand White rabbits. Dose levels of 0, 30, 150, or, 300 mg/kg were administered once daily on days 6–18 of presumed-

gestation (day 0 = day of insemination). Females were sacrificed on day 29 of presumed gestation. There were no deaths attributed to treatment. At the 150 mg/kg and 300 mg/kg levels, increased numbers of does with decreased motor activity and statistically significant numbers of does with ataxia were noted. At 300 mg/kg, a significant number of does had rales and an increased number of does showed labored breathing, perinasal substance, dried feces, impaired righting reflex, and red substance in the cage pan. These clinical observations were considered to be effects of treatment. Females in the 300 mg/kg group had statistically significant body weight loss for the entire dosage period. At 150 mg/kg, females lost weight on day 7 and 8 of presumed gestation. Although, compensatory weight gains occurred during the post-treatment period (days 19–29 of gestation), body weight gains remained statistically significantly reduced on days 6–29 of gestation in the 300 mg/kg group. No significant differences were obtained in litter averages for*corpora lutea*, implants, litter sizes, resorption sites, percent male fetuses, fetal body weight, percent resorbed conceptuses or number of does with any resorptions. No gross external, soft tissue or skeletal alterations in fetuses were considered to be related to treatment. The maternal NOAEL for technical dicamba to pregnant rabbits was 30 mg/kg/day. Levels of 150 and 300 mg/kg caused abortions, but were at significant maternally toxic doses. The developmental NOAEL was the highest dose tested, 300 mg/kg/day. There were no effects on embryo-fetal viability or development at any level.

ii. *Two-generation reproduction rat.* Potential effects on growth and reproductive performance were assessed over 2-generations of rats maintained on diets containing technical dicamba at concentrations of 0 control, 500, 1,500 or 5,000 ppm. Exposure at 5,000 ppm was associated with a slower growth rate of F1 pups prior to weaning and resulted in lower initial body weights in those selected as parental animals. The lower body weight was associated with a decrease in both food consumption and water intake. Sexual maturation was slightly delayed among males, but was likely associated with the initial reduced growth rate. Increased liver weights were noted consistently for adults of both generations and for weanlings. There were no effects on reproductive ability from treatment at any level. The low pregnancy rate among F, females in all groups was considered to be due to increased weights of those females. The NOAEL and LOAEL for system toxicity were 1,500 and 5,000 ppm, respectively. The NOAEL and LOAEL for reproductive toxicity were 500 (45 mg/kg/day) and 1,500 ppm, respectively.

4. *Subchronic toxicity*—i. *21–Day dermal.* There were no dicamba related changes in general behavior, appearance, body weight, or in blood and urine analysis. There were no compound-related gross pathology lesions, only skin lesions. There were no significant organ weight variations observed.

ii. *Thirteen-week rodent feeding* (rat). Rats were offered technical dicamba at dietary concentrations of 0, 1,000, 5,000, or 10,000 ppm. The mean body weight and food consumption values for the high dietary level animals were decreased from the control values. No adverse treatment-related findings were noted in either the blood parameters investigated or necropsy evaluation. Microscopic examinations of the liver revealed an absence or reduction of cytoplasmic vacuolation in the hepatocytes of the high dietary level animals. The no-effect level was suggested to be 5,000 ppm.

iii. *Eight-week rodent (dog).* Technical dicamba was offered orally at dietary concentrations of 0 (Control), 100, 500, or 2,500 ppm to dogs for 1 year. Initially, a decrease in food consumption was noted mainly among males at 500 and 2,500 ppm. This was most notable in a single 2,500 ppm male resulting in almost no food consumed for the first 3 weeks of feeding. Following administration of the 2,500 ppm diet in a water slurry during weeks 4–6, this male was placed back on feed and food consumption stabilized. There appears to be a limit to the amount of material that can be added to the feed before dogs will not consume the diet. The 2,500 ppm level was considered close to the maximum that could be employed, as 1 dog failed to consume the diet when offered in the usual form. Due mainly to the aforementioned male, mean body weight of 2,500 ppm males did not increase until week 5. The overall body weight gain for the 1 year period was comparable for all groups. It was concluded that aside from the lower food consumption, the no-effect level for toxicity was 50-60 mg dicamba/kg body weight (2,500 ppm) in both males and females. Because of the lack of toxicity shown in this study, the RfD Peer Review committee concurred that the NOEL was 2,500 ppm (HDT) and a LOEL was not established.

Sub-chronic neurotoxicity. NOAEL was established at 401 (m) and 472 (f) mg/kg/day. No histopathological effects on the peripheral or central nervous system were noted.

5. *Chronic toxicity*—i.*Chronic feeding/carcinogenicity in rat.* Groups of 60 rats/sex were maintained on diets containing technical dicamba at concentrations of either 0, 50, 250, or 2,500 ppm. An interim sacrifice of 10/sex/level was conducted at 12 months. Initially scheduled as a 27–month study, males were sacrificed at 115 weeks and females at 118 weeks due to survival rates. In males, no statistically significant differences in data for all tumors combined, all benign tumors combined, and all malignant tumors combined were obtained. A slight increase in malignant lymphoma was not statistically significant (pairwise comparisons), and was not considered to be toxicologically significant. A slight increase in thyroid parafollicular cell carcinoma in the high treatment group was noted but was not statistically significant in pairwise comparisons. In females, no statistically significant differences were noted in comparisons with all tumors combined, all benign tumors combined, and all malignant tumors combined or in any individual tumor type. In summary, no signs of toxicity related to administration of dicamba were noted. Findings among animals in the three treatment groups were considered to be comparable to findings among the control animals. Dicamba was not carcinogenic for animals of the species, strain, and age under the conditions of the study. Based on the results of the study, the no effect level was considered to be 2,500 ppm.

ii. *Carcinogenicity in mice.* Groups of 52 male and 52 female mice were fed diets containing dicamba at concentrations of 0, 50, 150, 1,000, or 3,000 ppm. Males were sacrificed following 89 weeks of feeding and females were sacrificed following 104 weeks of feeding. Reduced body weight gain (not statistically different) was noted among 3,000 ppm females. Increased mortality noted among 3,000 ppm males was considered unlikely to be related to treatment but could not be completely excluded. An increased incidence in lymphoid tumors, showing a statistical significance at 150 and 1,000 ppm, occurred in females. However, the incidence at 3,000 ppm did not statistically differ from control. Additionally, there was no significant trend with dosage and the values for treated females were within historical control data. Finally, the incidence of benign and malignant tumors in any tissue were similar for treated and control animals. Administration of dicamba in the diet at achieved intakes ranging from 5.5 to 364 mg/kg/day

produced no evidence of tumorigenic potential. Generally, no findings among mice receiving 1,000 ppm or below were considered to be of toxicological significance. The dietary level of 1,000 ppm (108 mg/kg/day in males and 121 mg/kg/day in females) was defined as the no toxic effect level. However, the RfD committee chose to establish the NOAEL at 3,000 ppm and stated that no LOAEL had been established.

iii. *Chronic dog.* In a 1–year chronic feeding study, dicamba 86.8% active ingredient (a.i.) was administered to Beagle dogs (4/sex/group) in the diet at 0, 10, 500 or 2,500 ppm (0, 2, 11, or 52 mg/kg/day) for 12 months. No adverse effects were observed at any dose level. No abnormalities in clinical signs, hematology, clinical chemistry, or urinalysis were reported. No abnormal findings were made at necropsy, nor were there any significant changes in food consumption or body weight. The NOAEL for this study is 52 mg/kg/day, the highest dose level tested. The LOAEL could not be established.

6. *Animal metabolism.* Dicamba has been tested in rats, dogs, cattle, goats, and hens. In all cases, dicamba is excreted very rapidly, mainly as unchanged dicamba and to a lesser extent as 3,6-dichloro-2-hydroxybenzoic acid with trace amounts of 3,6-dichloro-5-hydroxy-o-anisic acid. The results of these studies demonstrate that dicamba is not persistent and does not accumulate in animals.

7. *Metabolite toxicology.* Toxicity of the metabolites of dicamba to humans is concurrently evaluated during toxicity testing because both plant, and animal metabolites are formed during the course of toxicity tests. Both plant, and animal major metabolites are considered not of toxicological concern.

8. *Endocrine disruption.* No specific tests have been conducted with dicamba to determine whether the pesticide may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effect. However, available data have not implicated dicamba in such effects.

C. Aggregate Exposure

1. *Dietary exposure.* EPA has established the RfD for 3,6-dichloro-o-anisic acid (dicamba) at 0.045 mg/kg/day. This RfD is based on a 2–generation reproduction study in rat with a NOAEL of 45 mg/kg/day and an uncertainty factor of 1,000.

Cancer classification and risk assessment. The cancer classification of dicamba has been reviewed and recommended that the compound be classified as a Group D carcinogen, not classifiable as to human carcinogenicity.

i. *Food–chronic dietary exposure.* The estimated aggregate dietary exposure is based on the Theoretical Maximum Residue Contribution (TMRC) calculation. 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 residues are at the tolerances level. The dicamba TMRC for the overall U.S. population from the currently established and proposed tolerances represents approximately 23.9% of the RfD.

ii. *Drinking water.* EPA does not have monitoring data available to perform a quantitative drinking water risk assessment for dicamba at this time. A Tier 1 drinking water assessment of dicamba using the GENEEC model and the SCI-GROW model were run to produce estimates of dicamba concentrations in surface and ground water respectively. Estimated maximum concentrations of dicamba in surface and ground water are 98 and 0.013 ppb, respectively. The estimated concentrations of dicamba in surface and ground water are less than EPA's level of comparison for dicamba in drinking water as a contribution to chronic aggregate exposure. Therefore, taking into account present uses, and uses proposed in this action, BASF Corporation concludes with reasonable certainty that residues of dicamba in drinking water (when considered along with other sources of exposure for which there are reliable data), would not result in unacceptable levels of aggregate human health risk at this time.

iii. *Acute exposure and risk.* This acute dietary (food) risk assessment used the Dietary Exposure Evaluation Model (DEEM). Regulating at the 95th percentile, acute dietary exposure used up only 28.6% of the acute RfD. The risks from acute dietary exposures to dicamba do not exceed EPA's level of concern.

iv. *Chronic exposure and risk.* The chronic dietary exposure analysis from food sources was conducted using the RfD of 0.045 mg/kg/day. In conducting this chronic dietary risk assessment, EPA has made very conservative assumptions: 100% of RACs having dicamba tolerances will contain dicamba residues and those residues will be at the level of the established tolerance. This results in an overestimate of human dietary exposure. The chronic DEEM analysis used mean consumption (3–day average) data, and showed U.S. population (48 states) at only 23.9% of the RfD.

2. *Non-dietary exposure.* Dicamba (3,6-dichloro-o-anisic acid), is currently registered for use on outdoor residential and recreational turf. Application is made by both homeowners and professional applicators. There is a potential oral, inhalation, eye and dermal exposure to infants and children to dicamba from the registered uses for lawn and turfgrass weed control. These exposures are considered to be very low. Currently there are no inhalation or eye exposure data required for post-application of pesticides to lawns and turf. As inhalation exposure for mixer/loaders is acceptable, the risk to infants and children from inhalation exposure under a much lower exposure scenario is characterized qualitatively as being extremely low. Exposure data are required for hand to mouth movements of infants and children. As there are no chemical-specific or site-specific data available to determine the potential risks associated with residential exposures, the EPA has determined that residential exposure and risk are acceptable for dosages of 0.5 lb/A, based on a dermal NOAEL of 1,000 mg/kg/day and exposures of 0.051 mg/kg/day for low pressure hand wand, liquid formulations, and 0.079 mg/kg/day for granular formulations. For residential post-application exposure and risk assessment, EPA determined that the potential residential post-application risks for short-term and intermediate exposures did not exceed their level of concern. In this analysis both oral and dermal exposures, and risks for adults and infants from post-applications were determined. This analysis was based on assumptions and generic data from the Draft HED Standard Operating Procedures (SOPs) for Residential Exposure Assessments (December 18, l997). These SOPs rely on what are considered to be upper-percentile assumptions and intended to represent Tier 1 assessments.

D. Cumulative Effects

At this time, there is no available data to determine whether dicamba, and its metabolites 3,6-dichloro-5-hydroxy-o-anisic acid and 3,6-dichloro-o-2-hydroxybenzoic acid, have a common mechanism of toxicity with other substances or how to include this pesticide or its metabolites in a cumulative risk assessment. For the purposes of this tolerance action, therefore, BASF Corporation has not assumed that dicamba and its metabolites have a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population.* Using the conservative exposure assumptions described above and based on the

completeness and the reliability of the toxicity data, a risk assessment for chronic dietary exposure from food and feed uses was made for all subpopulations. The percentage of the RfD occupied is only approximately 23.9% for the general population and 71.1% for non-nursing infants the most exposed group.

2. *Infants and children.* There was evidence of increased susceptibility to the offspring following prenatal and/or postnatal exposure in the 2-generation reproduction study in rat. In this study, offspring toxicity was manifested as significantly decreased pup growth in all generations and mating at a dose lower than that which caused parental systemic toxicity (abortions and clinical signs of neurotoxicity). Available studies indicated no increase susceptibility of rats or rabbits in *in utero* exposure to dicamba. In a prenatal developmental toxicity study in rats, there was no evidence of developmental toxicity at the highest dose tested. In a prenatal developmental toxicity study in rabbits, developmental toxicity (irregular ossification of internasal bones), were only seen at the dose that caused maternal toxicity (abortions and neurotoxic clinical signs). Therefore, there is an adequate toxicity data base for dicamba and exposure data are complete or are estimated based on data that reasonably account for potential exposures. A ten-fold safety factor for increased susceptibility of infants and children was applied for chronic (long-term) exposure, and a three-fold safety factor was applied for acute (short- and intermediate-term) exposures to dicamba, due to evidence of increased susceptibility to the offspring following prenatal and/or postnatal exposure in the 2-generation reproduction study in rats. The uncertainty factor (FQPA Safety Factor) of ten-fold was reduced for acute dietary and short-term and intermediate-term residential exposures because the increased susceptibility was only observed in the reproduction study and not in the prenatal developmental studies. The FQPA Safety Factor was reduced to 3x for acute dietary risk assessment for all populations, including infants and children, because: (1) The endpoint of concern is clinical signs of neurotoxicity (in the absence of neuropathology) observed following a single oral exposure in an acute neurotoxicity study; (2) the increased susceptibility was seen in the offspring of parental animals receiving repeated oral exposures in a 2-generation reproduction toxicity study; and (3) no increased susceptibility was observed following *in utero* exposures of rats or rabbits in the developmental studies.

F. International Tolerances

No CODEX maximum residue levels have been established for dicamba.

[FR Doc. 01–31494 Filed 12–20–01; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–30517; FRL–6810–5]

Pesticide Products; Registration Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of applications to register pesticide products containing new active ingredients not included in any previously registered products pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Written comments, identified by the docket control number OPP–30517, must be received on or before January 22, 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. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–30517 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Rita Kumar, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8291; e-mail address: kumar.rita@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	Crop production Animal production
	311 32532	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 seassist 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 OPP–30517. 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 Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m.,