where infants and children would be at additional risk.

E. International Tolerances

Rohm and Haas is petitioning that Alkyl (C12-C20) Methacrylate copolymer be exempt from the requirement of a tolerance based upon the low risk polymer as per 40 CFR 723.250. Therefore, an analytical method to determine residues of Alkyl (C12-C20) Methacrylate copolymer in raw agricultural commodities has not been proposed.

We are not aware of any country requiring a tolerance for Alkyl (C12-C20) Methacrylate copolymer. Nor have there been any CODEX Maximum Residue Levels (MRL's) established for any food crops at this time. (Bipin Gandhi)

[FR Doc. 98–31068 Filed 11–19–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–846; FRL–6043–9]

BASF Corporation; Pesticide Tolerance Petition Filing

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 the docket control number PF–846, must be received on or before December 21, 1998.

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Divison (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under **SUPPLEMENTARY INFORMATION.** No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Joanne I. Miller, Product Manager 23, Herbicide Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 237, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305–6224; e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions 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.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–846] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number (PF–846) and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

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

Dated: November 4, 1998.

James Jones,

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 views of the petitioner. EPA is publishing the petition summaries verbatim without editing them 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.

BASF Corporation

PP 6F 4604 and 4F 3041/FAP 4H5428

EPA has received pesticide petitions (PP 6F 4604 and 4F 3041/FAP 4H5428) from BASF Corporation, 26 Davis Drive, Research Triangle Park, P.O. Box 13528, NC 27709, proposing pursuant to section 408 (d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR 180.227 by establishing and revising tolerances for residues of the herbicide dicamba (3,6-dichloro-o-anisic acid) and its two metabolites; 3,6-dichloro-5-hydroxy-o-anisic acid and 3,6-dichloro-2-hydroxybenzoic acid. The tolerances requested for residues in or on the following raw agricultural commodities are described as follows:

1. Revise tolerances for residues of dicamba (3,6-dichloro-o-anisic acid) and its metabolite 3,6-dichloro-5-hydroxy-o-anisic acid in or on: barley grain to 6 ppm, barley straw to 15 ppm; cottonseed to 3 ppm; wheat grain to 2 ppm, wheat straw to 30 ppm.

2. Establish new tolerances for residues of dicamba (3,6-dichloro-o-anisic acid) and its metabolite 3,6-dichloro-5-hydroxy-o-anisic acid in or on: barley hay at 2 ppm, corn, field, forage at 3 ppm; corn, field, stover at 3 ppm, corn, pop, stover at 3 ppm;

cottonseed meal at 5 ppm; Crop Group 17 (grass forage, fodder, and hay) forage at 125 ppm and hay at 200 ppm; oats forage at 80 ppm, oats hay at 20 ppm; wheat forage at 80 ppm, wheat hay at 20 ppm.

3. Revise tolerances for residues of dicamba (3,6-dichloro-o-anisic acid) and its metabolite 3,6-dichloro-2-hydroxybenzoic acid in or on: asparagus to 4 ppm.

4. Revise tolerances for residues of dicamba (3,6-dichloro-o-anisic acid) and its metabolites; 3,6-dichloro-2-hydroxybenzoic acid and 3,6-dichloro-5-hydroxy-o-anisic acid in or on: soybean seed to 10 ppm.

5. Establish new tolerances for residues of dicamba (3,6-dichloro-o-anisic acid) and its metabolites; 3,6-dichloro-2-hydroxybenzoic acid and 3,6-dichloro-5-hydroxy-o-anisic acid in or on: aspirated grain fractions at 5,100 ppm, and soybean hulls at 13 ppm.

6. Delete the following tolerances: grasses, hay at 40 ppm; grasses, pasture at 40 ppm; and grasses, rangeland at 40 ppm as these tolerances are being replaced by Crop Group 17 in point 2.

The proposed analytical methods involve extraction, partition, clean-up and detection of residues by gas chromatography/electron capture detector (gc/ecd). 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. 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-hydroxy-o-anisic acid. Tolerances are expressed as the dicamba parent and/or the respective 5-hydroxy and 2-hydroxy metabolites depending on the raw agricultural commodity of concern.

2. *Analytical method*. BASF Crop, 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*—i. *Plant*. Residue trials have been conducted with dicamba on the crops for expanded use requested in the subject petitions. Multiple salts of dicamba were studied in side-by-side testing to confirm that no effect on magnitude of the residues was caused by the salt formulation type of the dicamba. The tolerances listed in the first paragraph (section 1) are based on the maximum expected residue from geographically representative field trial data.

Only newly generated data, or data not implicated in the CRAVEN Laboratories indictment are used to support the subject petitions.

ii. *Animal*. The amended 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

Data are provided that are representative of the mammalian toxicity effects of dicamba and are part of the many studies conducted to support BASF Corp. assertion of safety of dicamba to humans.

1. *Acute toxicity*—i. Oral rat LD_{50}: 1879 mg/kg (m); 1581 mg/kg (f).

ii. Acute dermal rat LD_{50}: > 2,000 kg/kg (m/f).

iii. Acute inhalation rat LC_{50}: > 9.6 mg/L (m/f).

iv. *Primary eye irritation*: Extremely irritating and corrosive to the eye.

v. *Primary dermal irritation rabbits*. Not a primary skin irritant.

vi. *Dermal sensitization guinea pigs*. Moderate potential to cause dermal sensitization.

vii. *Acute neurotoxicity*. no observed adverse effect level (NOAEL) < 300 milligrams/kilogram (mg/kg) (low dose). No neuropathological effects were found.

2. *Genotoxicty— 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 (UDS with WI-38 human lung fibroblasts: Negative; Differential toxicity with *E. coli* polA 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 in ip injected rats insert text.

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 HDT and the NOAEL was 160 mg/kg/day.

4. *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 days 7-8 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 (HDT), 300 mg/kg/day.

There were no effects on embryo-fetal viability or development at any level.

5. *2-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 parts per million (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 lowest observed adverse effect level (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.

6. *Subchronic toxicity—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.

7. *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 NOAEL was suggested to be 5,000 ppm.

8. *Eight-week non-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 1st 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 one 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 NOAEL 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 reference dose (RfD) Peer review Committee concurred that the NOAEL was 2,500 ppm HDT and a LOAEL was not established. OPP's HED Branch is to decide if a new dog feeding study is required.

9. *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.

10. *Chronic toxicity—Chronic feeding/oncogenicity 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 oncogenic 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.

11. *Oncogenicity in mice.* Groups of 52 male and 52 female mice were fed diets containing dicamba at oncentrations of 0, 50, 150, 1,000, or 3,000 ppm. Males were killed following 89-weeks of feeding and females were killed 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.

12. *Estrogenic or other ndocrine effects.* 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.

13. *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.

14. *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.

C. Aggregate Exposure

1. *Dietary exposure*. Exposure from the use of Dicamba in the culture of wheat, barley, oats, millet, sorghum, corn, soybeans, grasses, cotton, sugarcane and asparagus crops is discussed under the below topics of food and drinking water.

2. *Food*. The subject petition amends these uses but does not add new crops. The potential dietary exposure of the population to residues of dicamba or its metabolites is calculated based on the Theoretical Maximum Residue Contribution (TMRC) for all crops with dicamba use. The TMRC is a worst case estimate of dietary exposure since it assumes that 100% of all crops for which tolerances are established are treated with dicamba, and that pesticide residues are present at the tolerance levels. The resulting dietary exposure estimate therefore overestimates exposure and is considered conservative. The number is then determined to be a percentage of the EPA decided RfD. Dietary exposure may occur from crop commodities and meat and milk. Based on the EPA DRES model BASF Corp. has estimated that the average U.S. population dietary exposure to dicamba to be only 1.87% of the RfD. This number is very low and considered very safe as an active ingredient is allowed up to 100% before less conservative risk assessment measures are initiated.

Acute dietary analysis compared the daily dietary exposure to the lowest NOAEL for acute and subchronic studies. EPA's current policy for Tier I analysis uses the conservative assumption that all residues are at a high end estimate or maximum, typically taken as the tolerance value. Acute dietary assessment for dicamba is made by comparing the ratio of exposure and the NOAEL from acute neurotoxicity of 300 mg/kg/day to achieve a Margin of Exposure (MOE). A MOE of 300 is required because a NOAEL was not reached in the acute neurotoxicity test. The following MOE values are obtained for key population subgroups.

Population Subgroup	Margin of Exposure
US Population	16000
Infants <1 year	13000
Children 1 to 6	13000
Females 13+ years	117000
Males 13+ years	110000

3. *Drinking water*. Dicamba has been used commercially for in excess of 30 years. From available public data, detections in ground water from commercial uses have been very low and infrequent. The typical level found in ground water is less than 5 ppb. This should be compared to the current Health Advisory Level (HAL) of 200 ppb and the anticipated HAL of 3,000 ppb under the newly revised RfD of 0.45 mg/kg/day.

These infrequent and low levels of detection in groundwater demonstrate that significant movement of dicamba is not likely and is not a considerable factor in assessing human health risk.

4. *Non-dietary exposure*. Non-dietary exposure would mainly occur from the use of dicamba for broadleaf weed control on residential or recreational turf. BASF is currently collecting data on the potential exposure from non-dietary sources such as residential turf use. However, no reliable information are currently available for risk assessment at this time. This petition is only related to already approved crop uses and therefore non-dietary route of exposure is not considered to be a factor in assessing additional human risk.

D. Cumulative Effects

Dicamba belongs to the benzoic acid class of compounds. There are no other compounds of this class in significant use and none in food use. Therefore, cumulative effects from dietary or non-occupational exposure from pesticides of similar chemistry are considered unlikely. BASF Corp. does not have reliable data to indicate a common mechanism of toxicity to other compounds. Therefore cumulative effects from common mechanisms of action are also unlikely.

E. Safety Determination

The RfD for dicamba is 0.45 mg/kg/day. The RfD is a level at or below which daily aggregate exposure over a lifetime will not cause appreciable human health risk. The estimates of exposure are based on conservative assumptions that all crops with a tolerance for dicamba are treated and that all residues found are at the maximum or tolerance level.

1. *U.S. population*. Using the conservative assumptions described above, BASF Corp. has estimated that the U.S. population dietary exposure to dicamba is 1.87% of the RfD.

2. *Infants and children*. Dicamba is not a reproductive or developmental toxicant. Therefore no specific effects on infants and children are expected. Based on the weight of evidence of the toxicity studies an additional safety factor is not warranted.

Using the conservative assumptions described above, BASF Corp. has estimated the dietary exposure to infants and children as percent of the RfD. From the current and new proposed use of dicamba dietary exposure for the most sensitive subgroups are 6.65% for non-nursing infants (<1-year old) and 4.6% for children 1-6 years old.

Aggregate exposure due to the combined residues in food, drinking water and non-dietary exposure through direct contact with residues in a residential setting (lawn) should be pursued through the use of a reserve risk approach. The elements for consideration are therefore estimated as follows:

- Food: Total Population 1.87%
  Non-nursing Infants <6yrs. 6.7%
- Water/Lawn: Low human risk.....expected to be inconsequential

BASF Corp. believes that the water and non-dietary exposure risk for the most sensitive subgroup is inconsequential due to demonstrated low findings in water relative to the HAL and low toxicity to humans with respect to oral, dermal and inhalation exposure.

Aggregate exposure is therefore estimated to be less than 10% of the RfD for the most sensitive population subgroup. Therefore, BASF Corp. concludes that there is reasonable certainty that no harm will result from aggregate exposure of residues of dicamba or its metabolites including all dietary and other non-occupational exposures.

F. International Tolerances

No international tolerances have been established under CODEX. Therefore there is no need to ensure consistency.

[FR Doc. 98–31070 Filed 11–19–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–836; FRL–6030–9]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.