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.

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ENVIRONMENTAL PROTECTION AGENCY

[PF–836; FRL–6030–9]

Notice of Filing of Pesticide Petitions

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 the docket control number PF–836, must be received on or before December 21, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (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 to: opp-docket@epamail.epa.gov. Follow 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. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: The product manager listed in the table below:

Product Manager	Office location/telephone number	Address
Mark Dow PM-03	Rm. 214, CM #2, 703–305–5533, e-mail:dow.mark@epamail.epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA
James Tompkins PM-25	Rm. 239, CM #2, 703–305–5697, e-mail:tompkins.james@epamail.epa.gov.	Do.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals 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 these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data 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–836] (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. Comments and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number (insert docket number) and appropriate petition number. Electronic comments on 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: October 27, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. 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.

1. Bayer Corporation

PP 8F5023

EPA has received a pesticide petition (PP 8F5023) from Bayer Corporation, 8400 Hawthorn Road, Kansas City, MO 64120, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of cyfluthrin: [cyano[4-fluoro-3-phenoxyphenyl]-methyl-3-[2,2-dichloroethenyl]-2,2-dimethyl-cyclopropanecarboxylate] in or on the raw agricultural commodity soybean, bean at 0.03 parts per million (ppm); soybean, forage at 8.0 ppm; soybean, hay at 4.0 ppm; field corn, forage at 3.0 ppm; and field corn, fodder at 6.0 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of cyfluthrin in plants is adequately understood. Studies have been conducted to delineate the metabolism of radiolabeled cyfluthrin in various crops all showing similar results. The residue of concern is cyfluthrin.

2. *Analytical method*. Adequate analytical methodology (gas/liquid chromatography with an electron capture detector) is available for enforcement purposes.

3. *Magnitude of residues*. Cyfluthrin is the active ingredient in the registered end-use product Baythroid 2 Emulsifiable Pyrethroid Insecticide, EPA Reg. No. 3125-351. Data to support the proposed tolerances have been submitted to the Agency.

B. Toxicological Profile

1. *Acute toxicity*. There is a battery of acute toxicity studies for cyfluthrin supporting an overall toxicity Category II for the active ingredient.

2. *Genotoxicty*. Mutagenicity tests were conducted, including several gene mutation assays (reverse mutation and recombination assays in bacteria and a Chinese hamster ovary (CHO)/HGPRT assay); a structural chromosome aberration assay (CHO/sister chromatid exchange assay); and an unscheduled DNA synthesis assay in rat hepatocytes. All tests were negative for genotoxicity.

3. *Reproductive and developmental toxicity*. An oral developmental toxicity study in rats with a maternal and fetal no observed adverse effect level (NOAEL) of 10 milligram/kilogram body weight/day (mg/kg/bwt/day) highest dose tested (HDT).

An oral developmental toxicity study in rabbits with a maternal NOAEL of 20 mg/kg/bwt/day and a maternal lowest effect level (LEL) of 60 mg/kg/bwt/day, based on decreased body weight gain and decreased food consumption during the dosing period. A fetal NOAEL of 20 mg/kg/bwt/day and a fetal LEL of 60 mg/kg/ bwt/day were also observed in this study. The LEL was based on increased resorptions and increased postimplantation loss.

A 3-generation reproduction study in rats with systemic toxicity NOAELs of 7.5 and 2.5 mg/kg/bwt/day for parental animals and their offspring, respectively. At higher dose levels (HDLs), the body weights of parental animals and their offspring were reduced.

4. *Subchronic toxicity*. A subchronic toxicity feeding study using rats demonstrated a NOAEL of 22.5 mg/kg/ bwt/day, the HDT.

A 6 month toxicity feeding study in dogs established a NOAEL of 5 mg/kg/ bwt/day. The LEL was 15 mg/kg/bwt/ day based on clinical signs and reduced thymus weights.

5. *Chronic toxicity*. A 12 month chronic feeding study in dogs established a NOAEL of 4 mg/kg/bwt/ day. The LEL for this study is established at 16 mg/kg/bwt/day, based on slight ataxia, increased vomiting, diarrhea and decreased body weight.

A 24 month chronic feeding/ carcinogenicity study in rats demonstrated a NOAEL of 2.5 mg/kg/ bwt/day and LEL of 6.2 mg/kg/bwt/day, based on decreased body weights in males, decreased food consumption in males, and inflammatory foci in the kidneys in females.

A 24 month carcinogenicity study in mice was conducted. Under the conditions of the study there were no carcinogenic effects observed. A 24 month chronic feeding/carcinogenicity study in rats was conducted. There were no carcinogenic effects observed under the conditions of the study.

6. *Animal metabolism*. A metabolism study in rats showed that cyfluthrin is rapidly absorbed and excreted, mostly as conjugated metabolites in the urine, within 48 hours. An enterohepatic circulation was observed.

7. *Metabolite toxicology*. No toxicology data have been required for cyfluthrin metabolites. The residue of concern is cyfluthrin.

8. *Endocrine disruption*. There is no evidence of endocrine effects in any of the studies conducted with cyfluthrin, thus, there is no indication at this time that cyfluthrin causes endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure— Food*. Dietary exposure was estimated using Novigen's Dietary Exposure Evaluation Model (DEEM) software; results from field trial and processing studies; consumption data from the USDA Continuing Surveys of Food Intake by Individuals (CSFIIs), conducted from 1989 through 1992; and information on the percentages of crops treated with cyfluthrin.

Cyfluthrin is currently registered for use in alfalfa, carrots, citrus, cotton, peppers, radishes, sorghum, sunflower, sugarcane, sweet corn, and tomatoes. In addition, it has an import tolerance for hops. Various formulations are registered for use in food handling establishments and in combination with another active ingredient, for use in field corn, pop corn and sweet corn. For potential cyfluthrin use on soybeans and field corn the impact on the exposure assessment was examined.

Chronic dietary exposure estimates with the current label uses for the overall U.S. population were 0.9% of the reference dose (RfD) (0.008 mg/kg/ bwt/day). When soybeans, field corn and potatoes were included the chronic dietary exposure estimates for the overall U.S. population were 0.8% of the RfD. For the most highly exposed population subgroups, non-nursing infants (<1 year) and children 1 to 6 years of age, the exposure was estimated to be 1.9% of the RfD and 1.8% of the RfD respectively for current label uses and 1.7% of the RfD and 1.7% of the RfD respectively for label uses plus potatoes, soybeans, field corn. The apparent drop in the percentage of the RfD when these uses are added may be explained by the lower limit of detection of the field trial data for these crops as opposed to the food handling data.

Acute dietary exposures were estimated for the overall U.S. population, females 13 years and older, children, ages 1-6, and 7-12 years, infants, non-nursing and nursing. The exposure was compared to the NOAEL of 20 mg/kg/ bwt/day to estimate the margin of exposures (MOEs).

For the all the population subgroups studies the 95th and 99.9th percentile of exposure the MOEs were calculated to be over 18,000 and 5,000 respectively for all current label uses and 9,900 and 3,800 respectively for all label uses plus potatoes, field corn and soybeans.

For women aged 13 years and older the 95th, and 99.9th percentile of acute exposure the MOEs were calculated as 66,746 and 18,390 respectively for all current label uses and 33,704 and 11,516 respectively for label uses plus potatoes, field corn, and soybeans.

Lastly, for the potentially highest exposed population subgroups, non-nursing infants (<1 year) and children ages 1-6 years, the 95th, and 99.9th percentile of acute exposure to the MOEs were calculated at 53,356; 18,346 and 5,179; 6,319 respectively for all current label uses and 19,624; 9,964 and 3802; 3943 respectively for label uses plus potatoes, field corn, and soybeans.

2. *Drinking water*. Cyfluthrin is immobile in soil, therefore, will not leach into groundwater. Additionally, due the insolubility and lipophilic nature of cyfluthrin, any residues in surface water will rapidly and tightly bind to soil particles and remain with sediment, therefore not contributing to potential dietary exposure from drinking water.

A screening evaluation of leaching potential of a typical pyrethroid was conducted using EPA's Pesticide Root Zone Model (PRZM3). Based on this screening assessment, the potential concentrations of a pyrethroid in ground water at 2 meters are essentially zero <0.001 parts per billion (ppb). Surface water concentrations for pyrethroids were estimated using PRZM3 and Exposure Analysis Modeling System (EXAMS) using standard EPA cotton runoff and Mississippi pond scenarios. The maximum concentration predicted in the simulated pond was 52 parts per trillion (ppt). Concentration in actual drinking water would be much lower. Based on these analyses, the contribution of water to the dietary risk estimate is negligible.

3. *Non-dietary exposure*. Non-occupational exposure to cyfluthrin may occur as a result of inhalation or contact from indoor residential, indoor commercial, and outdoor residential uses. Pursuant to the requirements of Federal Insecticide, Fungicide, and

Rodenticide Act (FIFRA) as amended by the Food Quality Protection Act (FQPA) of 1996 non-dietary and aggregate risk analyses for cyfluthrin were conducted. The analyses include evaluation of potential non-dietary acute application and post-application exposures. Non-occupational, non-dietary exposure was assessed based on the assumption that a flea infestation control scenario represents a ''worst case'' scenario. For the flea control infestation scenario indoor fogger, and professional residential turf same day treatments were included for cyfluthrin. Deterministic (point values) were used to present a worse case upper-bound estimate of non-dietary exposure. The non-dietary exposure estimates were expressed as systemic absorbed doses for a summation of inhalation, dermal, and incidental ingestion exposures. These worst-case non-dietary exposures were aggregated with chronic dietary exposures to evaluate potential health risks that might be associated with cyfluthrin products. The chronic dietary exposures were expressed as an oral absorbed dose to combine with the non-dietary systemic absorbed doses for comparison to a systemic absorbed dose NOAEL. Results for each potential exposed subpopulation (of adults, children 1-6 years, and infants <1 year) were compared to the systemic absorbed dose NOAEL for cyfluthrin to provide estimates of MOE.

The large MOEs for cyfluthrin clearly demonstrate a substantial degree of safety. The total non-dietary MOEs are 3,800, 2,700, and 2,500 for adults, children (1-6 years), and infants (<1 year), respectively. The aggregate MOE for adults is approximately 3,700 and the MOEs for infants and children exceed 2,400.

The non-dietary methods used in the analyses can be characterized as highly conservative. This is due to the conservatism inherent in the calculation procedures and input assumptions. An example of this is the conservatism inherent in the jassercise methodology's over-representation of residential post-application exposures. It is important to acknowledge that these MOEs are likely to significantly underestimate actual MOEs due to a variety of conservative assumptions and biases inherent in the derivatization of exposure by this method. Therefore, it can be concluded that large MOEs associated with potential non-dietary and aggregate exposures to cyfluthrin will result in little or no health risks to exposed persons. The aggregate risk analysis demonstrates compliance with the health-based requirements of the FQPA of 1996 for the current label uses. The additional use of cyfluthrin on field corn and soybean crops will have no impact on the analysis for non-dietary exposure.

D. Cumulative Effects

Bayer will submit information for EPA to consider concerning potential cumulative effects of cyfluthrin consistent with the schedule established by EPA at 62 FR 42020 (August 4, 1997) and other EPA publications pursuant to the FQPA.

E. Safety Determination

1. *U.S. population*. Based on the exposure assessments described above and on the completeness and reliability of the toxicity data, it can be concluded that total aggregate exposure to cyfluthrin from all label uses plus soybeans and field corn will utilize less than 2% of the RfD for chronic dietary exposures and that MOE in excess of 1,000 exist for aggregate exposure to cyfluthrin for non-occupational exposure. EPA generally has no concerns for exposures below 100% of the RfD, because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. MOE of 100 or more (300 for infants and children) also indicate an adequate degree of safety. Thus, it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to cyfluthrin residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of cyfluthrin, the data from developmental studies in both rat and rabbit and a 2-generation reproduction study in the rat can be considered. The developmental toxicity studies evaluate any potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates any effects from exposure to the pesticide on the reproductive capability of mating animals through 2-generations, as well as any observed systemic toxicity. The toxicology data which support these uses of cyfluthrin include:

i. A rat oral developmental toxicity study in which maternal and fetal NOAELs of 10 mg/kg/bwt/day HDT were observed.

ii. An oral developmental toxicity study in which rabbits had a maternal NOAEL of 20 mg/kg/bwt/day and a maternal LEL of 60 mg/kg/bwt/day, based on decreased body weight gain and decreased food consumption during the dosing period. A fetal NOAEL of 20 mg/kg/bwt/day and a fetal LEL of 60 mg/kg/bwt/day were also observed in this study. The LEL was based on increased resorptions and increased postimplantation loss.

iii. An oral developmental toxicity study performed with beta-cyfluthrin, the resolved isomer mixture of cyfluthrin, has been submitted to the Agency and is currently under review.

iv. A developmental toxicity study in rats exposed via inhalation to liquid aerosols of cyfluthrin revealed developmental toxicity, but only in the presence of maternal toxicity. The developmental NOAEL was 0.46 mg/m3 on the basis of reduced placental and fetal weights, and delayed ossification. The NOAEL for overt maternal toxicity was <0.46 mg/m3, the lowest dose tested (LDT).

In a rat 3-generation reproduction study, systemic toxicity NOAELs of 7.5 and 2.5 mg/kg/bwt/day for parental animals and their offspring, respectively, were observed. At higher dose levels, the body weights of parental animals and their offspring were reduced. Another multiple-generation reproduction study in rats has been submitted to the Agency and is currently under review.

To assess acute dietary exposure and determine a MOE for the overall U.S. population and certain subgroups, the Agency has used the rabbit developmental toxicity study which had a maternal NOAEL of 20 mg/kg/bwt/day. Because the toxicological endpoint is one of developmental toxicity, the population group of concern for this analysis was women aged 13 and above. This subgroup most closely approximates women of child-bearing age. The MOE is calculated as the ratio of the NOAEL to the exposure. The Agency calculated the MOE to be over 600. Generally, MOE's greater than 100 for data derived from animal studies are regarded as showing no appreciable risk.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children. The additional safety factor may be used when pre- and post-natal threshold effects were observed in studies or to account for incompleteness of the toxicity database.

The results of the 3-generation study in rats provided evidence suggesting that, with respect to effects of cyfluthrin on body weight, pups were more sensitive than adult rats. Thus, the Agency determined that an additional 3-fold uncertainty factor (UF) should be used in risk assessments to ensure adequate protection of infants and children.

Generally, the EPA considers MOE of at least 100 to indicate an adequate degree of safety. With an additional 3x UF, this would be 300 for infants and children. Using the exposure assessments described above and based on the described toxicity data aggregate exposure to infants and children indicate a margin of exposure in excess of 3,800. Thus, it can be concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to cyfluthrin residues.

F. Conclusions

The available data indicate that there is reasonable certainty of no harm from the aggregate exposure from all currently registered uses of cyfluthrin plus potatoes, field corn and soybeans.

G. International Tolerances

There are no Codex maximum residue levels (MRLs) currently established for residues of cyfluthrin on soybean commodities. There is a Codex MRLs for maize of 0.05 ppm.

2. Dow AgroSciences

PP 6F4784, PP 7F4856

EPA has received pesticide petitions (PP 6F4784 and PP 7F4856) from Dow AgroSciences, 9330 Zionsville Road, Indianapolis, IN 46268-1054, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of the herbicide diclosulam (N-(2,6-dichlorophenyl)-5-ethoxy-7-fluoro[1,2,4]triazolo[1,5-c]pyrimidine-2-sulfonamide) in or on the raw agricultural commodities soybean and peanut at 0.02 parts per million (ppm). EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petitions.

A. Residue Chemistry

1. *Plant metabolism*. Nature of residue studies demonstrated that residues of diclosulam would not be expected to accumulate to significant levels in soybeans or peanuts grown on soil treated with diclosulam, and that it was appropriate to base the magnitude of total terminal residues and proposed tolerances only on residues of the parent compound, diclosulam.

2. *Analytical method*. Analytical method is available for the determination of diclosulam in soybeans and peanuts at a limit of quantitation (LOQ) of 0.01 ppm that is suitable for the enforcement of the proposed tolerance of 0.02 ppm.

3. *Magnitude of residues*. No detectable residues of diclosulam are expected to result from soil applications to fields intended for soybeans or peanuts under the proposed maximum label conditions. On the basis of the limit of detection (LOD) of 0.003 ppm for diclosulam in the analytical method, a tolerance of 0.02 ppm is proposed for soybeans and peanuts. Soybeans and peanuts treated with 3 times the maximum label rates also resulted in no detectable residues of diclosulam in the soybean and peanuts or processed meal and oils. Thus, no tolerances are being proposed for diclosulam in any processed products.

B. Toxicological Profile

1. *Acute toxicity—Diclosulam acute toxicity is low*. The acute oral LD_{50} in the rat is >5,000 milligrams/kilogram (mg/kg) in both males and females and the acute dermal LD_{50} in the rabbit is >2,000 mg/kg. The inhalation LC_{50} in the rat is >5.04 mg/l of air. Diclosulam produced no indications of dermal irritation in rabbits or sensitization in the guinea pig, and only very slight transient eye irritation in the rabbit following acute exposure. End use formulations of diclosulam have similar low acute toxicity profiles.

2. *Genotoxicty*. In a battery of short-term *in vitro* genotoxicity tests (Ames, CHO/HGPRT, chromosomal aberration) and an *in vivo* cytogenetic assay, diclosulam was negative.

3. *Reproductive and developmental toxicity*. Diclosulam exhibited no effects on reproduction or fetal development. No effects on reproduction or fetal development in a multigeneration reproduction study in rats and no effects on reproductive performance or neonatal survival were seen at the highest dose tested (HDT) (limit test at 1,000 milligrams/kilogram/day (mg/kg/day). In a developmental toxicity study in rabbits, the maternal no observed adverse effect level (NOAEL) was 65 mg/kg/day and the developmental NOAEL was at least 650 mg/kg/day.

4. *Subchronic toxicity*. Thirteen-week dietary toxicity studies in rats, mice and dogs were conducted. The primary target organs identified in these studies were the kidneys (rat), and the liver (rat, mouse and dog). In the rat 13-week study the NOAELs were 50 mg/kg/day in the male and 100 mg/kg/day in the female, based on liver histopathologic evaluation in males and decreased body weights in females. In the mouse, the NOAEL was 100 mg/kg/day based upon hepatocellular hypertrophy. An NOAEL of 5 mg/kg/day was established in the dog based upon centrilobular hepatocellular hypertrophy at 25 mg/kg/day. In a 21-day repeated dermal application study in rabbits, diclosulam when given at a dose of 1,000 mg/kg/day produced no signs of dermal irritation or systemic toxicity.

5. *Chronic toxicity*. In a 2-year combined chronic toxicity/oncogenicity study in the rat, the NOAEL for chronic toxicity was 5 mg/kg/day based upon kidney effects characterized as slight, subtle alteration in kidney tubular morphology, mostly within the corticomedullary junction which likely represented more a physiologic adaptation than a pathological change indicative of a toxic injury. There was no evidence of an oncogenic response. In a 2-year dietary feeding study in B6C3F1 mice conducted at 50, 100, 250 and 500 mg/kg/day, 50 mg/kg/day was considered the NOAEL in males and the NOAEL in females based upon histologic changes in the kidney. The lesion noted in male mice was a reduced vacuolation of the kidney tubular epithelium at all dose levels. Decreased absolute and relative kidney weights were seen at 100 mg/kg/day and above. In female mice, focal dilation with hyperplasia of the lining epithelium of the renal cortical tubules was seen at 100 mg/kg/day and above. There was no evidence of an oncogenic response. In a 1-year chronic toxicity study in dogs, the NOAEL was considered 25 mg/kg/day, the HDT. Measurable toxicity was anticipated based on the results of the 13-week study in dogs; however, the only treatment related effects were slight elevations in serum alkaline phosphatase and creatinine levels at 25 mg/kg/day, which were considered within the normal limits of variability in dogs.

6. *Animal metabolism*. Metabolism studies conducted on diclosulam indicated over 80% of a single or repeated dose of 5 mg/kg was absorbed, while at 500 mg/kg/day, there was incomplete absorption of diclosulam, with only 15-20% of the dose absorbed. Urinary elimination was rapid with half-lives of approximately 7-12 hours. Sex dependent differences in disposition of the 5 mg/kg dose were traced to more efficient elimination of unchanged diclosulam in the female versus male kidney but are of no known toxicologic significance. Due to its rapid elimination, diclosulam has little potential to accumulate upon repeated administration.

7. *Metabolite toxicology*. The residue of concern for tolerance setting purposes is the parent material (diclosulam). Thus, there is no need to address metabolite toxicity.

C. Aggregate Exposure

1. *Dietary exposure—Food*. For Purposes of assessing the potential dietary exposure from use of diclosulam on soybeans and peanuts, a conservative estimate of aggregate exposure is determined by Theoretical Maximum Residue Contribution (TMRC) assuming that 100% of the soybeans and peanuts have a residue of diclosulam at the proposed tolerance level of 0.02 ppm. This results in an extremely conservative estimate of exposure for diclosulam, because no residues are expected in these commodities at the proposed maximum label rate. The potential dietary exposure is obtained by multiplying the tolerance residue level on soybeans and peanuts (0.02 ppm) by the consumption data which estimates the amount of soybean and peanut products consumed by various population subgroups. The maximum potential average daily dose (ADD) of diclosulam values determined for various populations are clearly significant overestimates compared with actual exposure. When ADDs are compared to the Reference Dose (RfD), which uses the lowest NOAEL of 5 mg/kg/day from the 2-year rat chronic toxicity study and an uncertainty factor of 100, the ADD for all U.S. consumers including the highest exposed group, non-nursing infants under 1-year old, would theoretically be exposed to about 0.1% of the RfD.

2. *Drinking water*. Another potential source of dietary exposure are residues in drinking water. Based upon the available field dissipation and field run off studies conducted with diclosulam there is little potential for exposure to diclosulam in drinking water to cause any human health concern.

D. Cumulative Effects

There is no reliable information to indicate that diclosulam has a common mechanism of toxicity with any other chemical compound or that potential toxic effects of diclosulam would be cumulative with those of any other pesticide chemical. Thus Dow AgroSciences believes it is appropriate to consider only the potential risks of diclosulam in its exposure assessment.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions described above, and based on the completeness and reliability of the toxicity data, Dow AgroSciences has concluded that aggregate exposure to diclosulam potentially can utilize about 0.1% of the RfD for non-nursing infants under 1-year old, theoretically the most exposed population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Therefore, Dow AgroSciences concludes that there is a reasonable certainty that no harm will result from aggregate exposure to diclosulam residues in on soybeans and peanuts and its processed products.

The complete toxicology profile for diclosulam shows no evidence of physiological effects characteristic of the disruption of the hormone estrogen. Based upon this observation, diclosulam does not meet the criteria for an estrogenic compound.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of diclosulam, data from developmental toxicity studies in rats and rabbits and a multigeneration reproduction study in the rat are considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability and potential systemic toxicity of mating animals and on various parameters associated with the well-being of offspring.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base. Based on the current toxicological data requirements, the data base for diclosulam relative to pre- and post-natal effects for children is complete. Further, for diclosulam, the NOAEL in the chronic feeding study which was used to calculate the RfD (5 mg/kg/day) is already lower than the NOAELs from the developmental studies in rats and rabbits by a factor of more than 200-fold.

Concerning the reproduction study in rats, there were no effects on reproduction or fetal development, even at a dose over 100 times the NOAEL used to establish the RfD. Therefore, Dow AgroSciences concludes that an additional uncertainty factor is not needed and that the RfD at 0.05 mg/kg/day is appropriate for assessing risk to infants and children.

Using the conservative exposure assumptions previously described, the percent RfD utilized by the aggregate (diet, and drinking water) exposure to residues of diclosulam on soybeans and peanuts is 0.000051 mg/kg/day for non-nursing infants under 1-year old, theoretically the most exposed population subgroup. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Dow AgroSciences concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to diclosulam on soybeans and peanuts.

F. International Tolerances

There are no Codex maximum residue levels established for residues of diclosulam on soybeans, peanuts or any other food or feed crop.

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ENVIRONMENTAL PROTECTION AGENCY

[PF–840; FRL–6039–6]

Dow AgroSciences LLC; Pesticide Tolerance Petition Filing

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 the docket control number PF–840, 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