

(a) Reflects priorities identified in the EPA and ORD strategic plans; (b) supports a reasonable balance in terms of attention to core research on multimedia capabilities and issues and to media-specific problem-driven topics; and (c) balances attention to near-term and to long-term research issues. In addition, the Committee will offer its advice on: (d) whether the objectives of the research and development program in ORD and the broader science and technology programs in EPA can be achieved at the resource levels requested; and (e) how can EPA use or improve upon the Government Performance and Results Act (GPRA) structure to communicate research plans, priorities, research requirements, and planned outcomes. A portion of the meeting will be devoted to development of the Committee's report.

**FOR FURTHER INFORMATION CONTACT:** Members of the public desiring additional information about the meeting should contact Dr. Jack Fowle, Designated Federal Officer, Research Strategies Advisory Committee (RSAC), Science Advisory Board (1400), Room 3702F, U.S. EPA, 401 M Street, SW, Washington, DC 20460; telephone/voice mail at (202) 260-8325; fax at (202) 260-7118; or via e-mail at <fowle.jack@epa.gov>. For a copy of the draft meeting agenda, please contact Ms. Wanda Fields, Management Assistant at (202) 260-4126 or by FAX at (202) 260-7118 or via e-mail at <fields.wanda@epa.gov>.

Materials that are the subject of this review are available from Mr. Mike Feldman of the Office of the Chief Financial Officer or from Mr. Lek Kadeli Office of Research and Development. Mr. Feldman can be reached on (202) 260-1179 or by e-mail at <feldman.mike@epa.gov> and Mr. Kadeli can be reached on (202) 564-6696 or via e-mail on <kadeli.lek@epa.gov>.

#### Providing Oral or Written Comments

Members of the public who wish to make a brief oral presentation to the Committee must contact Dr. Fowle in writing (by letter or by fax—see previously stated information) no later than 12 noon Eastern Time, Thursday, February 25, 1999 in order to be included on the Agenda. Public comments will be limited to five minutes per speaker or organization. The request should identify the name of the individual who will make the presentation, the organization (if any) they will represent, any requirements for audio visual equipment (e.g., overhead projector, 35mm projector,

chalkboard, etc), and at least 35 copies of an outline of the issues to be addressed or the presentation itself. The Science Advisory Board expects that public statements presented at its meetings will not repeat previously submitted oral or written statements. In general, each individual or group making an oral presentation will be limited to a total time of ten minutes. Written comments of any length may be submitted to the Committee up until the meeting.

#### The Science Advisory Board

Information concerning the Science Advisory Board, its structure, function, and composition, may be found in The FY1998 Annual Report of the Staff Director which is available from the SAB Committee Evaluation and Support Staff (CESS) by contacting US EPA, Science Advisory Board (1400), Attention: CESS, 401 M Street, SW, Washington, DC 20460 or via fax (202) 260-1889. Additional information concerning the SAB can be found on the SAB Home Page at: <http://www.epa.gov/sab>.

#### Meeting Access

Individuals requiring special accommodation at this meeting, including wheelchair access, should contact Dr. Fowle at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: February 9, 1999.

#### Donald G. Barnes,

*Staff Director, Science Advisory Board.*

[FR Doc. 99-3994 Filed 2-17-99; 8:45 am]

BILLING CODE 6560-50-P

#### ENVIRONMENTAL PROTECTION AGENCY

[PF-838; FRL-6036-4]

#### FMC Corporation; 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-838, must be received on or before March 22, 1999.

**ADDRESSES:** By mail submit written comments to: Information and Records Integrity Branch, Public Information 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 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:

James A. Tompkins, 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. 239, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305-5697 e-mail:

[tompkins.jim@epamail.epa.gov](mailto:tompkins.jim@epamail.epa.gov).

**SUPPLEMENTARY INFORMATION:** EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

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-838] (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-838) 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: February 10, 1999.

#### 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 FFDCFA. 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.

#### FMC Corporation

PP 7F4896

EPA has received a pesticide petition (PP 7F4896) from FMC Corporation, 1735 Market Street, Philadelphia, PA 19103, 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 clomazone in or on the raw agricultural commodities rice grain and rice straw at 0.05 parts per million (ppm). EPA has determined that the petition contains data or

information regarding the elements set forth in section 408(d)(2) of the FFDCFA; 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 clomazone in plants is adequately understood. The metabolism of clomazone has been studied in both monocotyledonous and dicotyledonous plant species, such as corn and soybeans. The residue of significance is the parent compound, clomazone. This picture is consistent with plant metabolism studies in other species (cotton, sweet potatoes, and tobacco), all of which have shown a similar metabolic pathway with the residue of significance being clomazone.

2. *Analytical method.* There is a practical analytical method for detecting and measuring levels of clomazone in or on rice grain, straw, and rice processed parts with a limit of detection that allows monitoring of food for residues at or above the levels proposed in this tolerance. Rice samples are analyzed using gas chromatography - mass selective detection with a limit of quantification of 0.02 ppm, for both straw and grain. Processed rice samples are analyzed using gas chromatography - nitrogen-phosphorous detector with a limit of quantification of 0.05 ppm.

3. *Magnitude of residues.* FMC conducted a residue study (consisting of 18 trials) to determine the magnitude of the residue of clomazone in/on rice grain and straw after treatment with one application of Command 3ME at 0.6 lb. ai/A at pre-plant, pre-emergent, or early post emergent. No detectable residues (detection limit = 0.01 ppm) of clomazone were found in rice grain or straw in any sample, irrespective of location or application method. A second study was conducted, using an excess rate of 1.25 lb. ai/A applied as a pre-emergent treatment, to determine the magnitude of the residue of clomazone in/on rice grain and the extent of concentration into its processed fractions. No detectable residues (detection limit = 0.01 ppm, limit of quantitation (LOQ) = 0.05 ppm) of clomazone were found in rice grain or any of the processed parts analyzed (polished rice, hulls or bran). Since no detectable residues were found in any rice raw agricultural or processed feed/ feedstuff commodities from the field studies, animal feeding studies in cow and poultry are not needed.

#### B. Toxicological Profile

1. *Acute toxicity.* The following mammalian toxicity studies have been conducted with clomazone technical (unless noted otherwise) to support registrations and/or tolerances of clomazone.

- i. A rat acute oral study with an LD<sub>50</sub> of 2,077 milligram kilogram (mg/kg) (male) and 1,369 mg/kg (female).
- ii. A rabbit acute dermal LD<sub>50</sub> of > 2,000 mg/kg.
- iii. A rat acute inhalation LC<sub>50</sub> of 6.25 mg/L (male), 4.23 mg/L (female) and 4.85 mg/L (combined sexes).
- iv. A primary eye irritation study in the rabbit which showed practically no irritation.
- v. A primary dermal irritation study in the rabbit which showed minimal irritation.

vi. A primary dermal sensitization study in the guinea pig which showed no sensitization.

Acute delayed neurotoxicity - clomazone, and its known metabolites, are not structurally related to known neurotoxic substances.

2. *Genotoxicity.* The following genotoxicity tests were all negative: Ames Assay; CHO/HGPRT Mutation Assay; and Structural Chromosomal Aberration. The Unscheduled DNA Synthesis genotoxicity was negative with activation; weakly positive without activation.

3. *Reproductive and developmental toxicity.* A 2-generation reproduction study was conducted in the rat with a parental systemic no observed adverse effect level (NOAEL) of 1,000 ppm (50 milligram kilogram day (mg/kg/day) based on decreased body weight (bwt) and food consumption at 2,000 ppm; and a progeny systemic NOAEL of 1,000 ppm (50 mg/kg/day) based on decreased pup bwt at 2,000 ppm. The reproductive performance NOAEL was > 4,000 ppm which was the highest dose tested (HDT). There was an unexplained decrease in the fertility index during mating of the F1b generation at 4,000 ppm which was not observed in the F1a litter or repeated in the F2 generation. Additionally, there was one F2a pup at 1,000 ppm which had non-functional hindlimbs and one F2b pup at 4,000 ppm which had extended hindlimbs with no flexion at the ankle. These limb abnormalities were not considered treatment-related for the following reasons, i) there was no dose response observed, ii) the findings were not statistically significant, iii) the findings were not repeated at the 1,000 ppm dose level in the F2b litter or found in the F1a or F1b litters, and iv) these findings or related hindlimb abnormalities were

not observed in developmental studies at gavage dose levels up to 100 mg/kg/day in the rat or 240 mg/kg/day in the rabbit.

A developmental toxicity study in rats given gavage doses of 100, 300 and 600 mg/kg/day and with maternal and fetal NOAELs of 100 mg/kg/day. The maternal NOAEL is based on decreased locomotion, genital staining and runny eyes and the developmental NOAEL is based on increased incidence of delayed ossification at 300 mg/kg/day. This study was negative for teratogenicity at all doses tested.

A developmental toxicity study in rabbits given gavage doses of 30, 240 and 700 mg/kg/day with maternal and fetal NOAELs of 240 mg/kg/day. The maternal NOAEL is based on a decrease in bwt and the developmental NOAEL is based on an increase in the number of fetal resorptions at 700 mg/kg/day. This study was negative for teratogenicity at all doses tested.

In all cases, the reproductive and developmental NOAELs were equal to the parental NOAELs, thus indicating that clomazone does not pose any increased risk to infants or children.

4. *Subchronic toxicity.* In a 90 day feeding subchronic study in mice the NOAEL was 20 ppm (<2.9 mg/kg/day) based on liver cytomegaly at 20 ppm.

5. *Chronic toxicity.* A 12 month feeding study in the dog with a NOAEL of 500 ppm (14.0 mg/kg/day for males; 14.9 mg/kg/day for females) based on increased blood cholesterol and liver weights at 2,500 ppm.

A 24 month chronic feeding/ oncogenicity study in the rat with a NOAEL of 100 ppm (4.3 mg/kg/day for males; 5.5 mg/kg/day for females) based on increased liver weights and increased liver cytomegaly at 500 ppm. There were no oncogenic effects observed under the conditions of the study.

A 24 month chronic feeding/ oncogenicity study in the mouse with a NOAEL of 100 ppm (15 mg/kg/day) based on an increase in the white blood cell count. There were no oncogenic effects observed under the conditions of the study.

Using the Guidelines for Carcinogen Risk Assessment, it is proposed that clomazone be classified as Group E for carcinogenicity (no evidence of carcinogenicity) based on the results of carcinogenicity studies in two species. In 24 month feeding/oncogenicity studies in rats and mice at dosages up to 2,000 ppm, there was no evidence of carcinogenicity. The NOAEL in the 24 month feeding/oncogenicity study in the rat was 100 ppm (4.3 mg/kg/day for males and 5.5 mg/kg/day for females).

The NOAEL in the 24 month feeding/ oncogenicity study in mice was 100 ppm (15 mg/kg/day). The studies were negative for carcinogenic effects at all dosage levels tested.

The reference dose (RfD) for clomazone has been established at 0.043 mg/kg/day. The RfD for clomazone is based on the 24 month feeding/ carcinogenicity study in the rat with a NOAEL of 4.3 mg/kg/day and an uncertainty factor of 100.

6. *Animal metabolism.* The metabolism of clomazone in animals is adequately understood. Clomazone degrades rapidly and extensively in rats, goats and poultry to a variety of metabolites which were readily excreted from the body via excreta.

7. *Metabolite toxicology.* No clomazone related metabolite residues have been identified as being of toxicological concern. The residue of significance is parent. Clomazone, has been thoroughly investigated in a full battery of studies including acute, genetic, reproduction developmental and oncogenic tests. These studies have demonstrated that clomazone has low acute toxicity, an overall absence of genotoxicity and does not cause reproductive toxicity, developmental toxicity or carcinogenicity.

8. *Endocrine disruption.* No specific tests have been conducted with clomazone to determine whether the herbicide may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects. It should be noted, however, that the chemistry of clomazone is unrelated to that of any compound previously identified as having estrogen or other endocrine effects. Additionally, a standard battery of required studies has been completed. These studies include an evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following repeated or long-term exposure. No endocrine effects were noted in any of these studies with clomazone.

### C. Aggregate Exposure

1. *Dietary exposure—Food.* For purposes of assessing the potential dietary exposure, EPA has estimated aggregate exposure based on the Theoretical Maximum Residue Contribution (TMRC) from the established tolerances for clomazone. 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 pesticide residues are present at the tolerance levels. Dietary exposure to

residues of clomazone in or on food will be limited to residues on cabbage (0.1 ppm), cottonseed (0.05 ppm), cucumber (0.1 ppm), succulent peas (0.05 ppm), peppers (0.05 ppm), pumpkins (0.1 ppm), soybeans (0.05 ppm), winter squash (0.1 ppm), summer squash (0.1 ppm), sweet potato (0.05 ppm), snap beans (0.05 ppm) and rice (0.05 ppm). Various feedstuffs from cotton and soybeans are fed to animals, thus exposure of humans to residues might result if such residues carry through to meat, milk, poultry or eggs. No tolerances are proposed for meat, milk, poultry or egg since no detectable residues from clomazone have been found in the past or were found in any rice raw agricultural commodity or processed animal feed products. As noted above, in conducting this exposure assessment, EPA has made very conservative assumptions, i.e., 100% of crops treated will contain clomazone residues and those residues would be at the level of the tolerance. It is FMC's opinion that these assumptions result in an overestimate of human exposure.

2. *Drinking water.* It is unlikely that there will be exposure to residues of clomazone through drinking water supplies. A field mobility study was conducted at a loamy sand location. Clomazone was found only in the top 0-1 ft. soil samples during the 61 day study period. No clomazone residue (<0.02 ppm) was detected in the deeper soil levels (1-2, 2-3 and 3-4 ft.). Mathematical modeling (PESTANS) was also applied to the loamy sand site. PESTANS showed very limited potential for movement of clomazone. That is, clomazone did not move lower than the top seven inches of soil over the first 30 days with 10 inches of precipitation and 100% recharge. Predictions were also obtained for other soil types including sand, sandy loam, silt loam and clay loam. These outputs yielded a similar conclusion, that clomazone has low potential for downward movement with its highest mobility being sand. The field leaching study and PESTANS modeling results were further confirmed by field dissipation studies conducted in silt loam (IL and AR), sandy loam (NJ), sandy clay loam (NC), silty clay loam (IA) and silt loam (LA) soils. Results of these studies demonstrated that clomazone tended to remain in the top soil layer (0-6"), with residues in the 6-12" layer being at or below method sensitivity (0.10 ppm) and generally declining to non-detectable. An aquatic field dissipation study conducted at locations in AR and TX, having silty

clay loam and loam soils characteristics respectively. Soil samples were taken over a period of 12 months following the herbicide application. Detectable residues of clomazone were found only in the 0-6" horizon. Should movement into surface water occur, potential for clomazone residues to be detected in drinking water supplies at significant levels is minimal. Results from an aquatic field dissipation study (static water situation) demonstrated half-lives of 12-13 days, indicating even shorter durations are likely under flowing water situations. Accordingly, there is no reasonable expectation that there would be an additional incremental aggregate dietary contribution of clomazone through groundwater or surface water.

3. *Non-dietary exposure.* Clomazone is only registered for use on food crops. Since the proposed use on rice is consistent with existing registrations, there will be no non-dietary, non-occupational exposure.

**D. Cumulative Effects**

Clomazone is an isoxazolidinone herbicide. No other registered chemical exists in this class of chemistry. Therefore, given clomazone's unique chemistry low acute toxicity, the absence of genotoxic, oncogenic, developmental or reproductive effects, and low exposure potential (see sections A and C), the expression of cumulative human health effects with clomazone and other natural or synthetic pesticides is not anticipated.

**E. Safety Determination**

1. *U.S. population.* Using the conservative exposure assumptions described above, based on the completeness and reliability of the toxicology data, it is concluded that aggregate exposure due to existing registered uses of clomazone will utilize less than one of the RfD for the U.S. population. Additionally, an analysis concluded that aggregate exposure to clomazone adding rice at a 0.05 ppm tolerance level will utilize 0.17% of the RfD for the U.S. 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. It is concluded that there is a reasonable certainty that no harm will result from aggregate exposure to residues of clomazone, including all anticipated dietary exposure.

2. *Infants and children.* Based on the current toxicological data requirements, the database relative to pre- and post-natal effects for children is complete (See section B.3). Further, for clomazone, the NOAEL in the 2 year feeding study which was used to calculate the RfD (0.043 mg/kg/day) is already lower than the NOAELs from the reproductive and developmental studies by a factor of more than 10-fold. Therefore, it can be concluded that no additional uncertainty factors are warranted and that the RfD at 0.043 mg/kg/day is appropriate for assessing aggregate risk to infants, children as well as adults.

Using the conservative exposure assumptions described above, FMC has concluded that the percent of the RfD that will be utilized by aggregate exposure to residues of clomazone in/on rice for non-nursing infants (< 1 year old), the population subgroup most sensitive, is 0.15 and the percent of the RfD that will be utilized by the children (1-6 years old) population subgroup is 0.037. The percent of the RfD utilized for infants and children for rice plus all other current clomazone tolerances is 0.640 and 0.286 respectively.

Based on the above information, FMC has concluded that there is a reasonable certainty that no harm will result to infants, children or adults from dietary food consumption exposure to clomazone residues from either rice foods alone or rice foods plus all other clomazone treated human dietary food sources.

**F. International Tolerances**

There are Codex residue limits for residues of clomazone in or on cottonseed, oilseed, peas, potatoes, rape, rice, soybeans, sugarcane, and tobacco. [FR Doc. 99-4025 Filed 2-17-99; 8:45 am]

BILLING CODE 6560-50-F

**ENVIRONMENTAL PROTECTION AGENCY**

[PF-859; FRL-6059-9]

**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-859, must be received on or before March 22, 1999.

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. 1132, 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. 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
Melody A. Banks (PM 03).	Rm. 205, CM #2, 703-305-5413, e-mail:banks.melody@epamail.epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA Do.
Joseph M. Tavano .....	Rm. 214, CM #2, 703-305-6411, e-mail: tavano.joseph@epamail.epa.gov.	