

ENVIRONMENTAL PROTECTION AGENCY

[FRL-6439-6]

Agency Information Collection Activities: Proposed Collection; Comment Request; Trade Secret Claims for Emergency Planning and Community Right-to-Know (EPCRA Section 322)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit the following proposed Information Collection Request (ICR) to the Office of Management and Budget (OMB): Trade Secret Claims for Emergency Planning and Community Right-to-Know (EPCRA Section 322) EPA ICR Number 1428.05. This ICR renews a previously approved ICR No. 1428.04 (expires March 31, 2000, OMB Control Number 2050-0078). Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before November 16, 1999.

FOR FURTHER INFORMATION CONTACT: Interested persons may obtain a copy of the ICR without charge by contacting Sicy Jacob, Chemical Emergency Preparedness and Prevention Office, SW, Washington DC 20460, 202-260-7249, fax no. 202-260-0927, or e-mail: Jacob.Sicy@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Affected entities: Entities potentially affected by this action are those who wish to file a claim of trade secrecy of reporting requirements under Section 322 of EPCRA. Entities may include chemical manufacturers, non-chemical manufacturers, petroleum refineries, etc.

Title: Trade Secret Claims for Emergency Planning and Community Right-to-Know (EPCRA Section 322), EPA ICR Number 1428.05.

Abstract: This information collection request pertains to trade secrecy claims submitted under Section 322 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA). EPCRA contains provisions requiring facilities to report to State and local authorities, and EPA, the presence and release of extremely hazardous substances (described in Sections 302 and 304), inventory of hazardous chemicals (described in Sections 311 and 312) and manufacture, process and

use of toxic chemicals (described in Section 313). Section 322 of EPCRA allows a facility to withhold the specific chemical identity from these EPCRA reports if the facility asserts a claim of trade secrecy for that chemical identity. The provision establishes the requirements and procedures that facilities must follow to request trade secrecy treatment of chemical identities, as well as the procedures for submitting public petitions to the Agency for review of the "sufficiency" of trade secrecy claims.

Trade secrecy protection is provided for specific chemical identities contained in reports submitted under each of the following EPCRA sections: (1) 303(d)(2)—Facility notification of changes that have or are about to occur, (2) 303(d)(3)—Local Emergency Planning Committee (LEPC) requests for facility information develop or implement emergency plans, (3) 311—Material Safety Data Sheets (MSDSs) submitted by facilities, or lists of those chemicals submitted in place of the MSDSs, (4) 312—Tier II emergency and hazardous chemical inventory forms, and (5) 313—Toxic chemical release inventory forms.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15.

The EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 9.9 hours per claim. The total annual burden for the respondents is 3,121 hours at a cost of

\$190,280. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Dated: September 10, 1999.

Jim Makris,

Director, Chemical Emergency Preparedness and Prevention Office.

[FR Doc. 99-24165 Filed 9-15-99; 8:45 am]

BILLING CODE 6560-50-M

ENVIRONMENTAL PROTECTION AGENCY

[PF-890; FRL-6098-3]

Notice of Filing a Pesticide Petition to Establish a Tolerance for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by docket control number PF-890, must be received on or before October 1, 1999.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the "SUPPLEMENTARY INFORMATION" section. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-890 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Jim Tompkins, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305-5697; and e-mail address: tompkins.jim@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information*A. Does this Action Apply to Me?*

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

| Categories | NAICS | Examples of potentially affected entities |
|------------|-------|---|
| Industry | 111 | Crop production |
| | 112 | Animal production |
| | 311 | Food manufacturing |
| | 32532 | Pesticide manufacturing |

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the "FOR FURTHER INFORMATION CONTACT" section.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "Federal Register--Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-890. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in

those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-890 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by E-mail to: "opp-docket@epa.gov," or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 5.1/6.1 or ASCII file format. All comments in electronic form must be identified by docket control number PF-890. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI.

Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the "FOR FURTHER INFORMATION CONTACT" section.

E. What Should I Consider as I Prepare My Comments for EPA.

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

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

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: September 7, 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 FFDCA. The summary of the petition was prepared by the petitioner and represents the views of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Zeneca Ag. Products

PP5F4554

EPA has received a pesticide petition [PP 5F4554] from Zeneca Ag. Products, 1800 Concord Pike, P. O. Box 15458, Wilmington, DE 19850-5458 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of sulfosate (the trimethylsulfonium (TMS) salt of glyphosate, also known as glyphosate-trimesium in or on the raw agricultural commodity (RAC) wheat grain at 10 parts per million (ppm) (of which no more than 2.5 ppm is TMS); wheat hay at 1 ppm (of which no more than 0.5 ppm is TMS); wheat straw at 90 ppm (of which no more than 40 ppm is TMS); wheat bran at 30 ppm (of which no more than 6 ppm is TMS); and wheat shorts at 20 ppm (of which no more than 5 ppm is TMS); and to increase the tolerance in poultry meat by-products to 0.5 ppm and in milk to 2 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 sulfosate has been studied in corn, grapes, and soybeans. EPA has concluded that the nature of the residue is adequately understood and that the

only residues of concern are the parent ions N-(phosphonomethyl)-glycine anion (PMG) and trimethylsulfonium cation.

2. *Analytical method.* Gas chromatography/mass selective (GC/MS) detector methods have been developed for PMG analysis in crops, animal tissues, milk, and eggs. GC detection methods have been developed for TMS in crops, animal tissues, milk, and eggs.

3. *Magnitude of residues in crops—Wheat.* Residue data are available for sulfosate in a total of 20 trials conducted in 8 EPA regions. The proposed tolerance of 1 ppm (of which no more than 0.5 ppm is TMS) for wheat hay; the proposed tolerance of 10 ppm (of which no more than 2.5 ppm is TMS) for wheat grain; and the proposed tolerance of 90 ppm (of which no more than 40 ppm is TMS) for wheat straw will accommodate any residue resulting from the proposed use pattern.

Wheat seed for processing were obtained and samples were processed. Analysis of the treated samples showed that residue of PMG and TMS concentrated in wheat bran, wheat shorts, and aspirated grain fractions. The proposed tolerance for wheat bran of 30 ppm (of which no more than 6 ppm is TMS) and the proposed tolerance for wheat shorts of 20 ppm (of which no more than 5 ppm is TMS) is adequate to accommodate any residues arising from this use pattern in wheat. No tolerances are required for wheat middlings or patent flour. Aspirated grain fractions (AGF) were also collected. Analysis of the treated samples showed that residue of both TMS and PMG concentrated in AGF, but the combined levels are less than the existing tolerance in 40 CFR 180.489 for AGF. No change in the existing tolerance is required.

4. *Magnitude of residue in animals—i. Ruminants.* The maximum dietary burden in dairy cows results from a diet comprised of 20% AGF, 60% wheat forage, 15% sweet corn stover, and 5% cotton gin byproducts for a total dietary burden of 427 ppm. The maximum dietary burden in beef cows results from a diet comprised of 20% AGF, 25% sweet corn stover, 25% sorghum grain, 25% wheat forage, and 5% cotton gin byproducts for a total dietary burden of 438 ppm. Comparison to a ruminant feeding study at a dosing level of 1,000 ppm indicates that the appropriate tolerance levels resulting from proposed additional uses are covered by existing tolerances in 40 CFR 180.489, except milk. The appropriate tolerance for milk is 2 ppm.

ii. *Poultry.* The maximum dietary burden in poultry results from a diet comprised of 80% sorghum grain and 20% soybean hulls for a total dietary burden of 43 ppm. Comparison to a poultry feeding study at a dosing level of 50 ppm indicates that the appropriate tolerance levels are covered by existing tolerances in 40 CFR 180.489, except poultry meat by-products. The appropriate tolerance for poultry meat by-product is 0.5 ppm.

B. Toxicological Profile

1. *Acute toxicity.* Several acute toxicology studies have been conducted placing technical grade sulfosate in Toxicity Category III and IV.

2. *Genotoxicity.* The toxicological endpoints for sulfosate are discussed in Unit 3.B. of the **Federal Register** notice of April 8, 1999 (64 FR 17171) (FRL 6071-2).

3. *Reproductive and developmental toxicity.* The toxicological endpoints for sulfosate are discussed in Unit 3.B. of the **Federal Register** notice of April 8, 1999 (FR 17171).

4. *Subchronic toxicity.* The toxicological endpoints for sulfosate are discussed in Unit 3.B. of the **Federal Register** notice of April 8, 1999 (64 FR 17171).

5. *Chronic toxicity.* The toxicological endpoints for sulfosate are discussed in Unit 3.B. of the **Federal Register** notice of April 8, 1999 (FR 17171).

6. *Animal metabolism.* The metabolism of sulfosate has been studied in animals. The residues of concern for sulfosate in meat, milk, and eggs are the parent ions PMG and TMS only.

7. *Metabolite toxicology.* There are no metabolites of toxicological concern. Only the parent ions, PMG and TMS are of toxicological concern.

8. *Endocrine disruption.* Current data suggest that sulfosate is not an endocrine disruptor.

C. Aggregate Exposure

1. *Dietary exposure—i. Food.* For the purposes of assessing the potential dietary exposure, Zeneca has utilized the tolerance level for all existing and pending tolerances; and the proposed maximum permissible levels of 10 ppm for wheat grain (of which no more than 2.5 ppm is TMS); 1 ppm for wheat hay (of which no more than 0.5 ppm is TMS); 90 ppm for wheat straw (of which no more than 40 ppm is TMS); 30 ppm for wheat bran (of which no more than 6 ppm is TMS); and 20 ppm for wheat shorts (of which no more than 5 ppm is TMS) and 100% crop treated acreage for all commodities. Assuming that 100% of foods, meat, eggs, and milk products

will contain sulfosate residues and those residues will be at the level of the tolerance results is an overestimate of human exposure. This is a very conservative approach to exposure assessment.

a. *Chronic exposure.* For all existing and pending tolerances; and the proposed maximum permissible levels proposed in this notice of filing, the potential exposure for the U.S. population is 0.04 milligrams/kilograms bodyweight/day (mg/kg bwt/day) (17.6% of reference dose (RfD)). Potential exposure for children's population subgroups range from 0.02 mg/kg bwt/day (7.8% of RfD for nursing infants (< 1 year old) to 0.12 mg/kg bwt/day (47.8%) for children 1-6 years old. The chronic dietary risk due to food does not exceed the level of concern (100%).

b. *Acute exposure.* The exposure to the most sensitive population subgroup, non-nursing infants, is 23.5% of the acute RfD at the 95th percentile. The acute dietary risk due to food does not exceed the level of concern (100%).

ii. *Drinking water.* Results from computer modeling indicate that sulfosate in ground water will not contribute significant residues in drinking water as a result of sulfosate use at the recommended maximum annual application rate (8.00 lbs a.i./acre). The computer model uses conservative numbers, therefore it is unlikely that ground water concentrations would exceed the estimated concentration of 0.014 parts per billion (ppb), and sulfosate should not pose a threat to ground water.

The surface water estimates are based on an exposure modeling procedure called GENEEC (Generic Expected Environmental Concentration). The assumptions of two applications of 4.00 lbs a.i./acre resulted in calculated estimated maximum concentrations of 58 ppb (acute, based on the highest 56-day value) and 10 ppb (chronic, average). GENEEC modeling procedures assumed that sulfosate was applied to a 10-hectare field that drained into a 1-hectare pond, 2-meters deep with no outlet.

As a conservative assumption, because sulfosate residues in groundwater are expected to be insignificant compared to surface water, it has been assumed that 100% of drinking water consumed was derived from surface water in all drinking water exposure and risk calculations. To calculate the maximum acceptable acute and chronic exposures to sulfosate in drinking water, the dietary food exposure (acute or chronic) was subtracted from the appropriate (acute or chronic) RfD. Drinking Water Levels

of Concern (DWLOCs) were then calculated using the maximum acceptable acute or chronic exposure, default body weights (70 kg - adult, 10 kg - child), and drinking water consumption figures (2 liters - adult, 1 liter - child).

The maximum concentration of sulfosate in surface water is 58 ppb. The acute DWLOCs for sulfosate in surface water were all greater than 5,400 ppb. The estimated average concentration of sulfosate in surface water is 10 ppb which is much less than the calculated levels of concern (> 1,300 ppb) in drinking water as a contribution to chronic aggregate exposure. Therefore, for current and proposed uses of sulfosate, Zeneca concludes with reasonable certainty that residues of sulfosate in drinking water would not result in unacceptable levels of aggregate human health risk.

2. *Non-dietary exposure.* Sulfosate is currently not registered for use on any residential non-food sites. Therefore, residential exposure to sulfosate residues will be through dietary exposure only.

D. Cumulative Effects

There is no information to indicate that toxic effects produced by sulfosate are cumulative with those of any other chemical compound.

E. Safety Determination

1. *U.S. population—i. Acute risk.* Since there are no residential uses for sulfosate, the acute aggregate exposure only includes food and water. Using the conservative assumptions of 100% of all crops treated and assuming all residues are at the tolerance level for all established and proposed tolerances, the aggregate exposure to sulfosate will utilize 12.3% of the acute RfD at the 95th percentile for the U.S. population. The estimated peak concentrations of sulfosate in surface and ground water are less than DWLOCs for sulfosate in drinking water as a contribution to acute aggregate exposure. Residues of sulfosate in drinking water do not contribute significantly to the aggregate acute human health risk considering the present uses and uses proposed in this action.

ii. *Chronic risk.* Using the conservative exposure assumptions described above, the aggregate exposure to sulfosate from food will utilize 17.6% of the chronic RfD for the U.S. population. The estimated average concentrations of sulfosate in surface and ground water are less than DWLOCs for sulfosate in drinking water as a contribution to chronic aggregate exposure. Residues of sulfosate in

drinking water do not contribute significantly to the aggregate chronic human health risk considering the present uses and uses proposed in this action.

2. *Infants and children.* The data base on sulfosate relative to prenatal and postnatal toxicity is complete. Because the developmental and reproductive effects occurred in the presence of parental (systemic) toxicity, these data do not suggest an increased prenatal or postnatal sensitivity of children and infants to sulfosate exposure. Therefore, Zeneca concludes, upon the basis of reliable data, that a 100-fold uncertainty factor is adequate to protect the safety of infants and children and an additional safety factor is unwarranted.

i. *Acute risk.* Using the conservative exposure assumptions described above, the aggregate exposure to sulfosate from food will utilize 23.5% of the acute RfD at the 95th percentile for the most highly exposed group, children (1-6 years). The estimated peak concentrations of sulfosate in surface and ground water are less than DWLOCs for sulfosate in drinking water as a contribution to acute aggregate exposure. Residues of sulfosate in drinking water do not contribute significantly to the aggregate acute human health risk considering the present uses and uses proposed in this action.

ii. *Chronic risk.* Using the conservative exposure assumptions described above, we conclude that the percent of the RfD that will be utilized by aggregate exposure to residues of sulfosate is 47.8% for children (1-6 years), the most highly exposed group. The estimated average concentrations of sulfosate in surface and ground water are less than DWLOCs for sulfosate in drinking water as a contribution to chronic aggregate exposure. Residues of sulfosate in drinking water do not contribute significantly to the aggregate chronic human health risk considering the present uses and uses proposed in this action.

F. International Tolerances

There are no Codex Maximum Residue Levels established for sulfosate. [FR Doc. 99-24168 Filed 9-15-99; 8:45 am]

BILLING CODE 6560-50-F