

any more susceptible than adult animals and the fact that the current RfD calculated from the NOAEL from the rat chronic study already incorporates a 300x uncertainty factor, Griffin believes that an adequate margin of safety is, therefore, provided by the RfD established by EPA. There is no evidence that propazine has endocrine-modulation characteristics as demonstrated by the lack of endocrine effects in developmental, subchronic, and chronic studies. There is no potential exposure to propazine via dietary, water, or non-occupational routes based on the proposed use on grain sorghum. No additional uncertainty factor for infants and children is warranted based on the completeness and reliability of the data base, the demonstrated lack of increased risk to developing organisms, and the lack of endocrine-modulating effects.

#### F. International Tolerances

There are no Codex Alimentarius Commission (CODEX) maximum residue levels (MRLs) established for residues of propazine and its chloro metabolites in or on raw agricultural commodities.

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2005-0140; FRL-7715-6]

### Tralkoxydim; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

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

**DATES:** Comments, identified by docket identification (ID) number OPP-2005-0140, must be received on or before July 22, 2005.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200

Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5697; e-mail address: [Tompkins.Jim@epa.gov](mailto:Tompkins.Jim@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

###### B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP-2005-0140. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment

system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic

public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

### C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2005-0140. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to [opp-docket@epa.gov](mailto:opp-docket@epa.gov), Attention: Docket ID Number OPP-2005-0140. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2005-0140.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP-2005-0140. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

### D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does

not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

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

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

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

## II. What Action is the Agency Taking?

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

### List of Subjects

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

Dated: June 1, 2005.

**Losi A. Rossi,**

Director, Registration Division, Office of Pesticide Programs.

### Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. 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.

### Syngenta Crop Protection, Inc.

#### Pesticide Petition (PP) 6F4631

EPA has received PP 6F4631 from Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC, 27419-8300 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.548 by establishing a tolerance for residues of tralkoxydim, 2-(Cyclohexen-1-one, 2-[1-(ethoxyimino)propyl]-3-hydroxy-5-(2,4,6-trimethylphenyl)-(9Cl), in or on the raw agricultural commodities barley grain, barley hay, wheat grain, and wheat hay at 0.02 parts per million (ppm) and barley straw, wheat forage, and wheat straw at 0.05 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 nature of the residue in barley, wheat, rotational crops, and livestock is adequately understood. The residues of concern for the tolerance expression are parent *per se*. Based on the results of animal metabolism studies it is unlikely that secondary residues would occur in animal commodities from the use of tralkoxydim on wheat and barley. Tralkoxydim rapidly metabolizes in plants, and no residues of parent are detected at harvest. Extensive metabolism in grain, forage and straw occurs, with that none of the individual metabolites exceeding 3.6% TRR.

2. *Analytical method.* An adequate analytical method, gas chromatography/mass spectrometry with selected ion

monitoring, is available for enforcement purposes.

3. *Magnitude of residues.* Magnitude of the residue trials conducted on spring wheat, winter wheat, and barley showed no detectable residues on wheat grain, straw, hay, forage, or processed commodities at the harvest timing prescribed by the label. Based on the results of animal metabolism studies it is unlikely that significant residues would occur in secondary animal commodities from the use of tralkoxydim on wheat and barley. The nature of the residue in plants is adequately understood.

#### B. Toxicological Profile

1. *Acute toxicity.* EPA has established an acute Reference Dose (RfD) for tralkoxydim of 0.3 milligrams/kilogram/day (mg/kg/day). This RfD is based on the no observed adverse effect level (NOAEL) of 30 mg/kg/day established in the rat developmental study and using an uncertainty factor of 100 based on 10X for interspecies extrapolation and 10X for intraspecies variation.

2. *Genotoxicity.* Tralkoxydim was negative for mutagenic/genotoxic effects in a Gene mutation Ames Assay in bacteria, a forward gene mutation in mouse lymphoma cells in culture, chromosome damage/*In vitro* assay in human lymphocyte cells, DNA damage repair *in vivo* assay in rat hepatocytes, and chromosome damage *in vivo* mouse micronuclei.

3. *Reproductive and developmental toxicity.* The developmental and reproductive toxicity data do not indicate increase susceptibility of rats or rabbits to in utero and/or postnatal exposure to tralkoxydim. A 3-generation rat reproduction study indicated a parental systemic NOAEL of 200 ppm (20 mg/kg/day) and a systemic lowest observed adverse effect level (LOAEL) of 1,000 ppm (100 mg/kg/day) based on reduced body weights and body weight gains in females. No reproductive toxicity was observed. A rat developmental study with a maternal NOAEL of 30 mg/kg/day and with a maternal LOAEL of 200 mg/kg/day based on maternal mortality, reduced body weights, and reduced food consumption and a developmental NOAEL of 30 mg/kg/day and a developmental LOAEL of 200 mg/kg/day based on reduced ossification of the centrum and hemicentrum, centrum bipartite, misshapen centra and fused centra. A rabbit developmental study with a maternal NOAEL of 20 mg/kg/day and a maternal LOAEL of 100 mg/kg/day based on reduced food consumption and a developmental NOAEL of 20 mg/kg/day and a

developmental LOAEL of 100 mg/kg/day based on abortions and increases in late resorptions.

4. *Subchronic toxicity.* Tralkoxydim is of low subchronic toxicity in 21-day dermal testing.

5. *Chronic toxicity.* EPA has established the RfD for tralkoxydim at 0.005 mg/kg/day. This RfD is based on NOAEL of 0.5 mg/kg/day in the chronic toxicity study in dogs with a 100-fold uncertainty factor to account for interspecies extrapolation (10x) and intraspecies variability (10x). The Health Effects Division Cancer Assessment Review Committee has classified Tralkoxydim in accordance with the Agency's *Proposed Guidelines for Carcinogen Risk Assessment* (April 10, 1996) as a "likely to be human carcinogen". This classification is based on the following factors:

i. Occurrence of benign Leydig cell tumors at all dose levels with the incidences at the high dose exceeding the concurrent and historical control range.

ii. Lack of an acceptable carcinogenicity study in a second species as required by Subdivision F Guidelines.

iii. The relevance of the testicular tumors to human exposure can not be discounted.

6. *Animal metabolism.* Based on the results of animal metabolism studies it is unlikely that significant residues would occur in secondary animal commodities from the use of tralkoxydim on wheat and barley

7. *Metabolite toxicology.* The nature of the residue in barley, wheat, rotational crops, and livestock is adequately understood. The residues of concern for the tolerance expression are parent *per se*.

8. *Endocrine disruption.* There has been no evidence of endocrine disruption concerns with resulting from tralkoxydim use on wheat and barley.

#### C. Aggregate Exposure

1. *Dietary exposure.* The proposed tolerances in or on the raw agricultural commodities: Barley grain, barley hay, wheat grain and wheat hay at 0.02 ppm, and barley straw, wheat forage and wheat straw at 0.05 ppm are the first to be established for tralkoxydim. There is no reasonable expectation of residues of tralkoxydim occurring in meat, milk, poultry, or eggs from its use on wheat and barley. Risk assessments were conducted by EPA to assess dietary exposures from tralkoxydim as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an

effect of concern occurring as a result of a one day or single exposure. An acute dietary risk assessment was conducted for tralkoxydim based on the NOAEL of 30 mg/kg/day from the rat developmental study. The acute dietary analysis using the Dietary Exposure Evaluation Model (DEEM™) computer program estimates that the distribution of single-day exposures utilizes 0.02% of acute RfD.

ii. *Chronic exposure and risk.* The RfD for Tralkoxydim is 0.005 mg/kg/day. This value is based on the systemic NOAEL of 0.5 mg/kg/day in the dog chronic feeding study with a 100-fold safety factor to account for interspecies extrapolation (10x) and intraspecies variability (10x).

2. *Food.* A DEEM™ chronic exposure analysis was conducted using tolerance levels for wheat and barley and assuming that 100% of the crop is treated to estimate dietary exposure for the general population and 22 subgroups. The chronic analysis showed that exposures from the tolerance level residues in or on wheat, and barley for children 1–6 years old (the subgroup with the highest exposure) would be 1.4% of the RfD. The exposure for the general U.S. population would be less than 1% of the RfD.

iii. A lifetime dietary carcinogenicity exposure analysis was conducted for tralkoxydim using the proposed tolerances along with the assumption of 100% of the crop treated and a  $Q^*$  of  $1.68 \times 10^{-2}$  (mg/kg/day)<sup>-1</sup>. A lifetime risk exposure analysis was also conducted using the DEEM™ computer analysis. The estimated cancer risk ( $5 \times 10^{-7}$ ) is less than the level that the Agency usually considers for negligible cancer risk estimates.

3. *Drinking water.* Drinking water estimated concentrations (DWECs) for surface water (parent tralkoxydim) were calculated by EPA's Pesticide Root Zone Model (PRIZM) computer models to be an average of 9.1 parts per billion (ppb). The DWECs for ground water based on the computer model screening concentration in ground water (SCI-GROW2) were calculated to be an average of .016 ppb.

4. *Non-dietary exposure.* There are no non-food uses of tralkoxydim currently registered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended. No non-dietary exposures are expected for the general population.

#### D. Cumulative Effects

EPA does not have, at this time, available data to determine whether tralkoxydim has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative

risk assessment. Tralkoxydim is structurally a cyclohexanedione. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, tralkoxydim does not appear to produce a toxic metabolite produced by other substances. For the purposes of these tolerances action, therefore, EPA has not assumed that tralkoxydim has a common mechanism of toxicity with other substances.

#### E. Safety Determination

1. *U.S. population — i. Acute risk.* The acute dietary analysis based on the NOAEL of 30 mg/kg/day from the rat developmental study using the DEEM™ computer program estimates that the distribution of single-day exposures utilizes 0.02% of acute RfD. The drinking water level of comparisons (DWLOCs) for acute exposure to tralkoxydim in drinking water calculated for females 13+ years old was 9,000 ppb. The estimated average concentration in surface water for tralkoxydim is 9 ppb. EPA's acute drinking water level of comparison is well above the estimated exposures for tralkoxydim in water for the subgroup of concern. For ground water, the estimated environmental concentrations (EEC's) using the SCI-GROW model were all less than 1 ppb.

ii. *Chronic risk.* A DEEM chronic exposure analysis showed that exposure from tolerance level residues in or on wheat, and barley for children 1–6 years old (the subgroup with the highest exposure) would be 1.4% of the RfD. The exposure for the general U.S. population would be less than 1% of the RfD. The DWLOCs for chronic exposure to tralkoxydim in drinking water calculated for U.S. population was 150 ppb and for children (1–6 years old) the DWLOC was 50 ppb. The estimated average concentration in surface water for tralkoxydim is 9 ppb. EPA's chronic drinking water level of concern is above the estimated exposures for tralkoxydim in water for the U.S. population and the subgroup of concern. Conservative model estimates (SCI-GROW) of the concentrations of tralkoxydim in ground water indicate that exposure will be minimal.

iii. *Cancer risk.* A DWLOC for cancer was calculated as 1 ppb. The estimated concentration in surface water and ground water for tralkoxydim for chronic exposure are 0.9 ppb (2.8 ppb (the 56-day concentration)/3) and 0.1 ppb, respectively. The model exposure estimates are less than the cancer DWLOC. EPA concludes that there is a reasonable certainty that no harm will

result from aggregate exposure to tralkoxydim residues.

2. *Infants and children.* The Agency concluded that an extra safety factor to protect infants and children is not needed based on the following considerations: The toxicology data base is complete for the assessment of special sensitivity of infants and children; the developmental and reproductive toxicity data do not indicate increase susceptibility of rats or rabbits to in utero and/or postnatal exposure; the NOAEL used in deriving the RfD is based on changes in liver function and morphology in male adult dogs (not developmental or neurotoxic effects) after chronic exposure and thus are not relevant for enhanced sensitivity to infants and children; unrefined dietary exposure estimates (assuming all commodities contain tolerance level residues) overestimate dietary exposure; model data used for ground and surface source drinking water exposure assessments result in estimates considered to be upper-bound concentrations; there are no registered uses for tralkoxydim that could result in residential exposures. EPA concludes that there is a reasonable certainty that no harm will result to children from aggregate exposure to tralkoxydim residues.

#### F. International Tolerances

There are no Codex Alimentarius Commission (Codex) or Mexican Maximum Residue Levels (MRLs) for tralkoxydim at this time.

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## ENVIRONMENTAL PROTECTION AGENCY

[FRL–7926–1]

### Environmental Justice Strategic Plan Framework and Outline

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Public comment period.

**SUMMARY:** The Office of Environmental Justice seeks public comment on: (1) The draft “Framework for Integrating Environmental Justice”; and (2) “Environmental Justice Strategic Plan Outline,” which includes proposed Environmental Justice Priorities (EJ Priorities). These two draft documents will be the foundation for the Environmental Justice Strategic Plan for 2006–2011. EPA is drafting the Environmental Justice Strategic Plan to integrate its environmental justice