

## 2. Non-dietary exposure.

Methoxyfenozide is not currently registered for use on any residential non-food sites. Therefore, there is no non-dietary acute, chronic, short-term or intermediate-term exposure.

### D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether methoxyfenozide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, methoxyfenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, it is assumed that methoxyfenozide does not have a common mechanism of toxicity with other substances.

### E. Safety Determination

1. *U.S. population.* Using the DEEM exposure assumptions described in this unit, Dow AgroSciences has concluded that aggregate exposure to methoxyfenozide from the proposed new tolerances will utilize 21.6% of the chronic PAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children 1 to 2 years old at 49.4% of the chronic PAD and is discussed below. EPA generally has no concern for exposures below 100% of the chronic PAD because the chronic PAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to methoxyfenozide in drinking water, the aggregate exposure is not expected to exceed 100% of the chronic PAD. Dow AgroSciences concludes that there is a reasonable certainty that no harm will result from aggregate exposure to methoxyfenozide residues.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of methoxyfenozide, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are

designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional ten-fold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (UF) (usually 100 for combine interspecies and intraspecies variability) and not the additional ten-fold MOE/UF when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

The toxicology data base for methoxyfenozide included acceptable developmental toxicity studies in both rats and rabbits as well as a 2-generation reproductive toxicity study in rats. The data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to methoxyfenozide. There is a complete toxicity data base for methoxyfenozide and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on the completeness of the data base and the lack of prenatal and postnatal toxicity, EPA determined that an additional safety factor was not needed for the protection of infants and children.

Since no toxicological endpoints were established, acute aggregate risk is considered to be negligible. Using the exposure assumptions described in this unit, Dow AgroSciences has concluded that aggregate exposure to methoxyfenozide from the proposed new tolerances will utilize 49.4% of the cPAD for infants and children. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the

potential for exposure to methoxyfenozide in drinking water, Dow AgroSciences does not expect the aggregate exposure to exceed 100% of the cPAD. Short and intermediate term risks are judged to be negligible due to the lack of significant toxicological effects observed. Based on these risk assessments, Dow AgroSciences concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to methoxyfenozide residues.

### F. International Tolerances

There are no Codex or Canadian maximum residue levels (MRLs) established for residues of methoxyfenozide. Mexican MRLs are established for residues of methoxyfenozide in cottonseed (0.05 ppm) and maize (0.01 ppm). The U.S. tolerances on these commodities are 2.0 ppm and 0.05 ppm, respectively. Based on the current use patterns, the U.S. tolerance levels cannot be reduced to harmonize with the Mexican MRLs, so incompatibility will exist.

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0157; FRL-7371-7]

### S-metolachlor; 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 ID number OPP-2004-0157, must be received on or before September 13, 2004

**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:** Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number:

(703) 305-7610; e-mail address: [jackson.sidney@epa.gov](mailto:jackson.sidney@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 28532)

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. **EPA Docket.** EPA has established an official public docket for this action under docket ID number OPP-2004-0157. 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, 1921 Jefferson Davis Hwy., 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 on 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-2004-0157. 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, Attention: Docket ID number OPP-2004-0157. 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-2004-0157.

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, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP-2004-0157. 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: August 4, 2004.

**Lois Rossi**

*Director, Registration Division, Office of Pesticide Programs.*

#### **Summary of Petition**

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3), except in this notice, the full text of the petition summary is incorporated by reference. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position 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.

#### **Interregional Research Number 4 (IR-4)**

*PP 3E6787*

EPA has received a pesticide petition (3E6787) from IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390 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 180.368(a)(2) by establishing tolerances for combined residues (free and bound) of the herbicide S-metolachlor acetamid, 2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)-, (S) and its metabolites, determined as the derivatives, 2-(2-ethyl-6-methylphenyl)amino-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound, S-metolachlor, in or on the following raw agricultural commodities (RACs):

1. Brassica, head and stem, subgroup 5A at 0.5 parts per million (ppm).
2. Cattle, fat at 0.04 ppm; cattle, kidney at 0.20 ppm; cattle, meat at 0.04 ppm; cattle, meat byproducts, except kidney at 0.04 ppm.
3. Corn, field, grain at 0.10 ppm; corn, field, stover at 6.0 ppm; corn, field, forage at 6.0 ppm; corn, sweet, forage at 6.0 ppm; corn, sweet, stover at 6.0 ppm; corn, pop, stover at 6.0 ppm; corn, pop, grain at 6.0 ppm; corn, sweet, kernel plus cob with husk removed at 0.1 ppm.
4. Cotton, gin byproducts at 4.0 ppm; cotton, undelinted seed at 0.1 ppm.
5. Egg at 0.04 ppm.
6. Garlic, bulb at 0.1 ppm.

7. Goat, fat at 0.04 ppm; goat, kidney at 0.20 ppm; goat, meat at 0.04 ppm; goat, meat byproducts, except kidney at 0.04 ppm.

8. Horse, fat at 0.04 ppm; horse, kidney at 0.20 ppm; horse, meat at 0.04 ppm; Horse, meat byproducts, except kidney at 0.04 ppm.

9. Leaf petioles subgroup 4B at 0.10 ppm.

10. Milk at 0.02 ppm.

11. Onion, dry bulb at 0.1 ppm; onion, green at 2.0 ppm.

12. Pea and bean, dried shelled, except soybean, subgroup 6C at 0.1 ppm.

13. Peanut at 0.2 ppm; peanut, hay at 20 ppm; peanut, meal at 0.40.

14. Poultry, fat at 0.04 ppm; poultry, meat at 0.04 ppm; poultry, meat byproducts, except liver at 0.04 ppm.

15. Safflower, seed at 0.1 ppm.

16. Shallot at 0.1 ppm.

17. Sheep, fat at 0.04 ppm; sheep, kidney at 0.20 ppm; sheep, meat at 0.04 ppm; sheep, meat byproducts, except kidney at 0.04 ppm.

18. Sorghum grain, stover at 4.0 ppm; sorghum grain, forage at 1.0 ppm; sorghum grain, grain at 0.3 ppm.

19. Soybean, seed at 0.2 ppm; soybean, forage at 5.0 ppm; soybean, hay at 8.0 ppm.

20. Vegetable, foliage of legume, except soybean, subgroup 7A at 15 ppm.

21. Vegetable, fruiting, group 8 at 0.5 ppm.

22. Vegetable, legume, edible podded, subgroup 6A at 0.5 ppm.

23. Vegetable, root, except sugar beet, subgroup 1B at 0.3 ppm.

24. Vegetable, tuberous and corm, subgroup 1C at 0.2 ppm.

IR-4 proposes to amend 40 CFR 180.368(a)(2) by removing tolerances established for the combined residues (free and bound) of the herbicide S-metolachlor acetamid, 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl)-, (S) and its metabolites, determined as the derivatives, 2-(2-ethyl-6-methylphenyl)amino-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound, S-metolachlor, in or on the following RACs: Carrot, roots at 0.20 ppm; horseradish at 0.20 ppm; onion, green at 0.20; rhubarb at 0.10 ppm; Swiss chard at 0.10 ppm; celery at 0.10 ppm; and tomato at 0.1 ppm.

IR-4 also proposes, upon approval of the aforementioned tolerances, to amend 40 CFR 180.368(b)(2) by deleting the time-limited tolerance for the combined residues (free and bound) of the herbicide S-metolachlor [(S)-2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl) acetamide], its

R-enantiomer and its metabolites, determined as the derivatives, 2-(2-ethyl-6-methylphenyl)amino-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound, in or on the RAC sweet potato, roots at 0.2 ppm.

Additionally, IR-4 proposes to amend 40 CFR 180.368(d) by establishing tolerances for combined residues (free and bound) of the herbicide S-metolachlor acetamid, 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-1-methylethyl)-, (S) and its metabolites, determined as the derivatives, 2-(2-ethyl-6-methylphenyl)amino-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound, S-metolachlor, in or on the following RACs:

1. Animal feed, nongrass, group 18 at 1.0 ppm.

2. Barley, grain at 0.1 ppm; barley straw at 0.1 ppm.

3. Buckwheat, grain at 0.1 ppm.

4. Oat, forage at 0.5 ppm; oat, grain at 0.1 ppm; oat straw at 0.5 ppm.

5. Peanut, meal at 0.4 ppm.

6. Rice, grain at 0.1 ppm; rice, straw at 0.5 ppm.

7. Rye, forage at 0.5 ppm; rye, grain at 0.1 ppm; rye straw at 0.5 ppm.

8. Wheat, forage at 0.5 ppm; wheat grain at 0.1 ppm; wheat straw at 0.5 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 support granting of the petition. Additional data may be needed before EPA rules on the petition. This notice includes a summary of the petition prepared by the registrant, Syngenta Crop Protection, 410 Swing Road, Greensboro, NC 27419. For a detailed discussion of the petitioner's synopsis of the science findings from environmental and human health assessments of this agricultural pesticide, please refer to the **Federal Register** of August 13, 2003 (68 FR 48373) (FRL-7320-9), "S-Metolachlor; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food."

[FR Doc. 04-18553 Filed 8-12-04; 8:45 am]

**BILLING CODE 6560-50-S**

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-7800-9]

### State Program Requirements; Revisions to the National Pollutant Discharge Elimination System (NPDES) Program; LA

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

**ACTION:** Proposal to Approve Revisions to the Louisiana Pollutant Discharge Elimination System Program.

**SUMMARY:** Pursuant to a request by the Environmental Protection Agency (EPA) and as required by the regulations, the State of Louisiana has submitted a request for approval of revisions to the Louisiana Pollutant Discharge Elimination System (LPDES) program, which was originally approved on August 26, 1996. Through the submission of the revised program authorization documents, including a complete program description, a Memorandum of Agreement (MOA) with EPA Region 6, and an Attorney General's Statement, the Louisiana Department of Environmental Quality (LDEQ) seeks approval of the proposed revisions to the LPDES program. Today, EPA Region 6 is providing public notice of its intent to approve the proposed revisions to the LPDES program and announcing a 30-day public comment period on the proposed revisions accompanied by an opportunity for a public hearing, if requested. EPA will either approve or disapprove the State's request based upon the requirements after considering all comments received. EPA and LDEQ want the citizens of Louisiana to understand the proposed revisions to the LPDES program and encourage public participation in the decision making process. Therefore, EPA requests that the public review the revised program documents and provide any appropriate comments.

**DATES:** The public comment period on the revised LPDES program will be from the date of publication until September 13, 2004. Comments must be received or post-marked by no later than midnight on September 13, 2004. A public hearing will be held if there is significant public interest based upon requests received prior to the end of the 30-day public comment period.

**ADDRESSES:** Send all paper copy comments to: Diane Smith, Water Quality Protection Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202. Comments may also be submitted electronically to the following e-mail address: