

will utilize 44% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD. Therefore, based on the completeness and reliability of the toxicity data, and the conservative exposure assessment, BASF concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of sethoxydim, including all anticipated dietary exposure and all other non-occupational exposures.

2. *Infants and children*—i.

Developmental toxicity was observed in a developmental toxicity study using rats but was not seen in a developmental toxicity study using rabbits. In the developmental toxicity study in rats a maternal no observed adverse effect level (NOAEL) of 180 milligrams/kilograms/day (mg/kg/day) and a maternal lowest observed adverse effect level (LOAEL) of 650 mg/kg/day (irregular gait, decreased activity, excessive salivation, and anogenital staining) was determined. A developmental NOAEL of 180 mg/kg/day and a developmental lowest effect level (LEL) of 650 mg/kg/day (21 to 22% decrease in fetal weights, filamentous tail and lack of tail due to the absence of sacral and/or caudal vertebrae, and delayed ossification in the hyoids, vertebral centrum and/or transverse processes, sternbrae and/or metatarsals, and pubes). Since developmental effects were observed only at doses where maternal toxicity was noted, the developmental effects observed are believed to be secondary effects resulting from maternal stress.

ii. *Reproductive toxicity*. A 2-generation reproduction study with rats fed diets containing 0, 150, 600, and 3,000 ppm (approximately 0, 7.5, 30, and 150 mg/kg/day) produced no reproductive effects during the course of the study. Although the dose levels were insufficient to elicit a toxic response, the Agency has considered this study usable for regulatory purposes and has established a free-standing NOAEL of 3,000 ppm (approximately 150 mg/kg/day), Proposed Rule of March 15, 1995, (60 FR 13941) (FRL-4936-1)

iii. *Reference dose*. Based on the demonstrated lack of significant developmental or reproductive toxicity BASF believes that the RfD used to assess safety to children should be the same as that for the general population, 0.09 mg/kg/day. Using the conservative exposure assumptions described above, BASF has concluded that the most sensitive child population is that of children ages 1 to 6. BASF calculates the exposure to this group to be

approximately 96% of the RfD for all uses (including those proposed in this document). Based on the completeness and reliability of the toxicity data and the conservative exposure assessment, BASF concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the residues of sethoxydim, including all anticipated dietary exposure and all other non-occupational exposures.

F. *International Tolerances*

A maximum residue level has not been established by the Codex Alimentarius Commission for residues of sethoxydim on the crops included in this proposal.

[FR Doc. 02-19983 Filed 8-6-02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-2139; FRL-7186-5]

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-2002-2139, must be received on or before September 6, 2002.

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**. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-2139 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-6224; e-mail address: miller.joanne@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 codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing 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 under **FOR FURTHER INFORMATION CONTACT**.

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," "Regulations and Proposed Rules," 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/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket ID number OPP-2002-2139. 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 ID number OPP-2002-2139 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, 1200 Pennsylvania Ave., NW., 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 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket ID number OPP-2002-2139. 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 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 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: July 29, 2002.

Peter Caulkins,

Acting 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 Syngenta Crop Protection Inc. and represents the view of Syngenta. 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.

Syngenta Crop Protection, Inc.

Interregional Research Project Number #4

PP 2F6443, PP 2E6465

EPA has received pesticide petitions 2F6443 and from Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419-8300 and 2E6465 from the Interregional Research Project Number #4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902 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 mesotrione, 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione, in or on the raw agricultural commodities popcorn, sweet corn ears, sweet corn forage, and sweet corn stover at 0.01, 0.01, 0.50, and 2.0 parts per million (ppm); respectively. EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petitions.

A. Residue Chemistry

1. *Plant metabolism.* The nature of the residue of mesotrione in plants is

adequately understood. Mesotrione is rapidly and completely metabolized in corn. No single extract or component accounted for greater than 0.01 ppm in grain. Numerous components were characterized in forage and fodder, including the metabolite 2-amino-4-methylsulfonyl benzoic acid (AMBA) and its conjugates and 4-methylsulfonyl-2-nitrobenzoic acid (MNBA).

2. *Analytical method.* Adequate analytical methods (HPLC- fluorescence method and HPLV-MS-MS) are available for enforcement purposes.

3. *Magnitude of residues.* The appropriate number of field residue studies were conducted with popcorn and sweet corn grown in 12 states. These trials were conducted in the major U.S. growing areas for popcorn and sweet corn.

B. Toxicological Profile

A full description of the studies describing the toxicity, animal metabolism, metabolite toxicology, and endocrine disruption of mesotrione can be found in the posting for its first tolerances in the **Federal Register** of June 21, 2001 (66 FR 33187) (FRL-6787-7)

C. Aggregate Exposure

1. *Dietary exposure.* For purposes of assessing the potential dietary exposure under the proposed tolerance, Syngenta estimated aggregate exposure based on the theoretical maximum residue concentration (TMRC) in popcorn, field corn, and sweet corn. The TMRC is calculated by multiplying the proposed tolerance levels for corn by the consumption data which estimate the amount of the commodity consumed by various population subgroups. Exposure was calculated only for the chronic exposures, since EPA has previously determined that mesotrione is not acutely toxic and no toxic reference dose was selected.

i. *Food.* Chronic exposure to mesotrione is negligible. Syngenta has conservatively assumed that 100% of all popcorn, field, and sweet corn used for human consumption would contain tolerance level residues of mesotrione. The potential dietary exposure to mesotrione was calculated on the basis of the proposed tolerance of the LOQ, 0.01 ppm, in corn. Residues in milk, meat and eggs due to the feeding of popcorn, field, and sweet corn commodities are not expected and tolerances for milk, meat and eggs are not required. However, exposure estimates took into consideration the transfer of minute residues from feed commodities into meat and dairy

products. Calculated on this basis, the dietary exposure of the general U.S. population to mesotrione would correspond to 2.5% of the chronic reference dose. The percent of the reference dose that will be utilized by dietary exposure to residues of mesotrione is 1.4% for nursing infants less than 1 year old, 5.8% for non-nursing infants and 6.2% for children 1 to 6 years old. It is concluded, there is reasonable certainty that no harm will result from the additional tolerances on popcorn, and sweet corn.

ii. *Drinking water.* Based on EPA's "Interim Guidance for Conducting Drinking Water Exposure and Risk Assessments" document (December 2, 1997), chronic drinking water levels of comparison (DWLOC) for mesotrione were calculated. The calculated DWLOCs for the U.S. population in general was 24.45 parts per billion (ppb). The most sensitive sub population was children between 1 to 6 years old with a chronic DWLOC of 6.96 ppb. The highly conservative model estimated water concentrations by FQPA Index Reservoir Screening Tool (FIRST) were 27 to 95 times lower than all the DWLOCs including the most sensitive group. It is, therefore, concluded that the potential impact of mesotrione residues in drinking water derived from either surface water or ground water on the aggregate risk to human health is negligible.

2. *Non-dietary exposure.* Mesotrione is not registered for any non-food use, and no significant non-dietary, non-occupational exposure is anticipated.

D. Cumulative Effects

Mesotrione is the only registered pesticide from the triketone chemical class, and mesotrione does not produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, mesotrione does not have a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population.* Mesotrione is not acutely toxic, no acute PAD has been selected, and no acute assessment is warranted. Under the most conservative estimates, the dietary exposure of the general U.S. population to mesotrione would be no more than 2.5% of the chronic reference dose. Highly conservative model estimated water concentrations by FIRST were 27 to 95 times lower than all the DWLOCs including the most sensitive group. It is, therefore, concluded that the potential impact of mesotrione residues derived from either dietary or water sources on

the aggregate risk to human health is negligible.

2. *Infants and children.* EPA previously determined that there is quantitative evidence of increased susceptibility demonstrated in the oral prenatal developmental toxicity studies in rats, mice, and rabbits. Delayed ossification was seen in the fetuses at doses below those at which maternal toxic effects were noted. Maternal toxic effects in the rat were decreased body weight gain during treatment and decreased food consumption and in the rabbit, abortions and gastrointestinal (GI) effects. The Food Quality Protection Act (FQPA) 10x safety factor was retained. Syngenta has summarized new data in the popcorn, and sweet corn petition to support the position that the default FQPA safety factor of 10x should not be applied to mesotrione. There is direct evidence that has been accepted by EPA that the mouse is the most appropriate model for predicting potential effects of mesotrione-induced elevation of tyrosine in humans, based on the similarity of the key tyrosine catabolism enzyme, tyrosine aminotransferase (TAT), in mice and humans. Furthermore, there is direct evidence to indicate that all the biological processes needed to regulate tyrosine levels in neonates are developed at birth, and TAT levels are comparable to the degree of expression in adults. Therefore, there is no compelling evidence to indicate that developing organisms are more sensitive to mesotrione administration than adults.

F. International Tolerances

There are no codex maximum residue levels established for residues of mesotrione on popcorn, and sweet corn, nor are there maximum residue levels established in Canada or Mexico.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0164; FRL-7189-9]

Pesticide Emergency Exemptions; Agency Decisions and State and Federal Agency Crisis Declarations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted or denied emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use of pesticides as listed in this notice. The