

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Among other changes, FQPA established a stringent health-based standard (“a reasonable certainty of no harm”) for pesticide residues in foods to assure protection from unacceptable pesticide exposure and strengthened health protections for infants and children from pesticide risks.

During 1998 and 1999, EPA and the United States Department of Agriculture (USDA) established a subcommittee of the National Advisory Council for Environmental Policy and Technology (NACEPT), the Tolerance Reassessment Advisory Committee (TRAC), to address FFDCA issues and implementation. TRAC comprised more than 50 representatives of affected user, producer, consumer, public health, environmental, states, and other interested groups. The TRAC met from May 27, 1998, through April 29, 1999.

In order to continue the constructive discussions about FFDCA, EPA and USDA established, under the auspices of NACEPT, the Committee to Advise on Reassessment and Transition (CARAT). The CARAT provided a forum for a broad spectrum of stakeholders to consult with and advise the Agency and the Secretary of Agriculture on pest and pesticide management transition issues related to the tolerance reassessment process. The CARAT was intended to further the valuable work initiated by earlier advisory committees toward the use of sound science and greater transparency in regulatory decision-making, increased stakeholder participation, and reasonable transition strategies that reduce risks without jeopardizing American agriculture and farm communities.

As a result of the 1998 and 1999 TRAC process, EPA decided that the implementation process and related policies would benefit from providing notice and comment on major science policy issues. The TRAC identified nine science policy areas it believed were key to implementation of tolerance reassessment. EPA agreed to provide one or more documents for comment on each of the nine issues by announcing their availability in the **Federal Register**. In a notice published in the **Federal Register** of October 29, 1998 (63 FR 58038) (FRL-6041-5), EPA described its intended approach. Since then, EPA has issued a series of draft and revised documents concerning the nine science policy issues. Publication of this notice is intended to update the public on the status of the science paper “Guidance for Submission of Probabilistic Human

Health Exposure Assessments to the Office of Pesticide Programs.”

### III. Why this Policy is No Longer Needed

Historically, assessment of the potential health risks associated with exposure to pesticides has focused upon single pathways of exposure (e.g., from pesticide residues in food, water, or residential/non-occupational uses) for individual chemicals, and not on the potential for individuals to be exposed to multiple pesticides by all pathways concurrently. In 1996, the FQPA required EPA to consider potential human health risks from all pathways of dietary and non-dietary exposures to more than one pesticide acting through a common mechanism of toxicity.

The “Guidance for Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs” was issued in 1998; <http://www.epa.gov/fedrgstr/EPA-PEST/1998/November/Day-05/6021.pdf>. The “Guidance for Submission of Probabilistic Human Health Exposure Assessments” provided general guidance on the conduct of probabilistic risk assessments. The guidance was intended to be used chiefly by persons conducting human health exposure assessments for purposes of registration or reregistration of pesticides.

EPA is withdrawing the “Guidance for Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs” because it has been superseded by several other EPA policy and guidance documents. These include: (1) “General Principles for Performing Aggregate Exposure and Risk Assessments,” <http://www.epa.gov/pesticides/trac/science/aggregate.pdf>, and (2) “Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity,” [http://epa.gov/pesticides/trac/science/cumulative\\_guidance.pdf](http://epa.gov/pesticides/trac/science/cumulative_guidance.pdf).

The “General Principles for Performing Aggregate Exposure and Risk Assessments” focus upon describing principles to guide the way in which aggregate exposure and risk assessment may be performed when more extensive distributional data and more sophisticated exposure assessment, methods and tools are available.

The “Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity” provides guidance for OPP scientists for evaluating and estimating the potential human risks associated with such multi-chemical and multi-pathway exposures to pesticides.

The policies and guidance mentioned above reflect EPA’s most recent guidance, thus superseding the information in “Guidance for Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs.” While the information in the document we are withdrawing is not necessarily inaccurate, it is outdated.

This action is also responsive to the recommendations made by EPA’s Office of Inspector General during its review of EPA’s implementation of FQPA. In its report “Opportunities to Improve Data Quality and Children’s Health through the FQPA” issued January 10, 2006 <http://www.epa.gov/oig/reports/2006/20060110-2006-P-00009.pdf> the Office of Inspector General Recommended that EPA should update the status of its science policy issue papers. This **Federal Register** notice updates the public on the status of one of the science policy papers which has been superseded by other guidance.

#### List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: June 30, 2009.

**James Jones,**

*Acting Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.*  
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**BILLING CODE 6560-50-S**

#### ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2009-0467; FRL-8424-7]

#### Lead Wheel Balancing Weights; TSCA Section 21 Petition; Notice of Receipt and Request for Comment

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

**ACTION:** Notice.

**SUMMARY:** This notice announces that EPA has received a petition under section 21 of the Toxic Substances Control Act (TSCA), and requests comments on issues raised by the petition. The petition was received from the Ecology Center of Ann Arbor, Michigan and the Sierra Club et al., (petitioners) on May 29, 2009. The petition requests that EPA establish regulations prohibiting the manufacture, processing, and distribution in commerce of lead wheel balancing weights. EPA must either grant or deny the petition within 90 days of filing.

**DATES:** Comments must be received on or before July 30, 2009

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2009-0467, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2009-0467. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to docket ID number EPA-HQ-OPPT-2009-0467. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. 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. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

*Docket:* All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

**FOR FURTHER INFORMATION CONTACT:** *For general information contact:* Colby Linter, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

*For technical information contact:* Mark Henshall, National Program Chemicals Division (7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-0523; e-mail address: [henshall.mark@epa.gov](mailto:henshall.mark@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. General Information**

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

This action is directed to the public in general. This action may, however, be of interest to you if you manufacture, process, distribute or use lead wheel balancing weights or are an automobile tire retailer. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the

technical person listed under **FOR FURTHER INFORMATION CONTACT**.

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

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM that you mail to EPA, 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 claimed as CBI. In addition to one complete version of the comment that includes 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. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

##### **II. TSCA Section 21**

###### *A. What is a TSCA Section 21 Petition?*

Under section 21 of TSCA (15 U.S.C. 2620), any person can petition EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule under TSCA section 4, 6, or 8 or an order under TSCA section 5(e) or 6(b)(2). A TSCA section 21 petition must set forth the facts that are claimed to establish

the necessity for the action requested. EPA is required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the **Federal Register**. A petitioner may commence a civil action in a U.S. district court to compel initiation of the requested rulemaking proceeding within 60 days of either a denial or if EPA fails to grant or deny the expiration of the 90-day period.

#### *B. What Criteria Apply to a Decision on a TSCA Section 21 Petition?*

Section 21(b)(1) of TSCA requires that the petition "set forth the facts which it is claimed establish that it is necessary" to issue the rule or order requested. 15 U.S.C. 2620(b)(1). Thus, TSCA section 21 implicitly incorporates the statutory standards that apply to the requested actions. In addition, TSCA section 21 establishes standards a court must use to decide whether to order EPA to initiate rulemaking in the event of a lawsuit filed by the petitioner after denial of a TSCA section 21 petition. 15 U.S.C. 2620(b)(4)(B). Accordingly, EPA will refer to the standards in TSCA section 21 and in the provisions under which actions have been requested to evaluate this petition.

### **III. Summary of TSCA Section 21 Petition Received**

#### *A. What Action was Requested?*

On May 29, 2009, EPA received a petition from the Ecology Center and the Sierra Club et al., petitioning EPA to establish regulations prohibiting the manufacture, processing, and distribution in commerce of lead wheel balancing weights ("wheel weights").

The petition and information submitted by the petitioner(s) is included in the docket at <http://www.regulations.gov>, under EPA-HQ-OPPT-2009-0467.

#### *B. What Support Do the Petitioners Offer?*

This petition incorporates by reference a previous petition submitted by the Ecology Center on May 13, 2005 (OPPT-2005-0032) (70 FR 35667, June 21, 2005) (FRL-7720-5), which requested a very similar action. In that petition, the Ecology Center asked EPA to prohibit the manufacturing, processing, distribution in commerce, and use and improper disposal of lead wheel balancing weights. EPA denied that petition on August 8, 2005.

The petitioners note that they have previously highlighted that automobiles

are a significant contributor of ongoing lead releases to the environment. The previous petition identified lead wheel balancing weight failure (weights falling off rims into roadways) as one of the largest ongoing releases of lead to the environment. The previous petition also noted that lead is consistently found to be in high concentrations on roadways and in end-of-life, vehicle waste (commonly called Auto Shredder Residue (ASR)). The petitioners also commented that lead wheel balancing weights are the second largest ongoing use of lead in vehicles and play a significant role in the release of lead to the environment.

The petitioners also note that on August 29, 2008 EPA announced its voluntary National Lead-Free Wheel Weight Initiative (NLFWWI). The Initiative's 40 charter members and four subsequent members include every new car manufacturer, four domestic lead wheel balancing weight producers (3M, Hennessy, Perfect, and Plombco), two leading tire manufacturers (Bridgestone Firestone and Goodyear) and major retailers (Bridgestone Firestone, Goodyear, Costco, Wal-Mart, and Sam's Club). These organizations committed in writing to:

- Identify the volume of lead to be eliminated.
- Reduce the use of lead for wheel balancing weights by December 31, 2011.
- Take responsibility for providing information, education, and outreach to the public, regarding the benefits of using lead-free wheel balancing weights.
- Properly collect and recycle used lead wheel balancing weights in their current inventory or acquired through normal business operation.
- Publicly endorse the NLFWWI and encourage the use of lead-free wheel balancing weights by others.

Petitioners cited EPA's National Lead-Free Wheel Weight Initiative web page which states:

- 12.5 million pounds of lead from wheel balancing weight is uncontrolled or unmanaged in the environment.
- 1.6 million pounds of lead is lost when wheel balancing weights fall off during normal driving conditions such as hitting a pot hole.
- 10.9 million pounds is sold or given to hobbyists for recreational purposes.

Petitioners estimate that no more than one-third of the lead wheel weight market would potentially be changed to lead-free due to the NLFWWI.

Petitioners also point to recent state actions to address wheel balancing weights. The petition notes that on April 28, 2009, the State of Washington instituted a ban on lead wheel balancing

weights effective January 1, 2011 and that California, Iowa, and Maine have similar proposals under consideration. The petition also stated that in 2008, Vermont banned lead wheel balancing weights on state-owned vehicles by January 1, 2010 and in new motor vehicles as of January 1, 2011.

### **IV. EPA Seeks Public Comment**

Under TSCA section 21, EPA must either grant or deny a petition within 90 days. EPA is providing this opportunity for the public to comment on, or provide any additional information relevant to, the issues identified in the petition. In order for the Agency to consider such comments within the 90-day petition review period, EPA must receive the comments by July 30, 2009 (see **ADDRESSES**).

In particular, EPA seeks information on the following:

- Quantitative information, data and/or case examples (e.g., recent scientific and technical studies, including analytical data results, analyses of environmental impacts, and statistical analyses) associated with the potential environmental releases to the air, surface water, ground water, and soil (particularly regarding potential releases within 1 mile of roadways, and potential releases to particularly sensitive environments or human and ecological populations) from lead wheel balancing weights and the following alternatives to lead tire weights: Steel tire weights; zinc alloy wheel balancing weights; plastic metal composite wheel balancing weights; and tin wheel balancing weights.
- Quantitative information and data (scientific and technical studies, including analytical data results, analysis of environmental impacts, statistical analyses, etc.) associated with releases of lead to the air, surface water, ground water, and soil within 1 mile of roadways from wheel balancing weights and all other sources.
- Information on whether the following list of potential exposure routes associated with releases from lead (and other alternative material) wheel balancing weights is complete or accurate, and whether other possible exposure routes associated with such releases should be considered: Dust in and near roadways; dust from roadways migrating to residential front yards, being tracked into houses and inhaled and/or ingested by children; wheel balancing weights and/or particles swept up by municipal street cleaners being incinerated, leading to increased levels of lead in air; wheel balancing weights and/or particles swept up by municipal street cleaners and land

filled, leading to increased levels of lead in ground water; vapors from home smelting of used wheel balancing weights obtained from gas stations and small tire retailers; wheel balancing weights left on cars that may be collected and burned in electric arc furnaces, releasing lead vapor and particulate matter to the air; releases associated with auto shredder activities (e.g., residues released to air or water); and releases from roadways to streams resulting in potential exposures to aquatic and terrestrial species.

- Quantitative or anecdotal information on the current availability and suitability of lead-free wheel balancing weights as alternatives, in both original equipment and aftermarket settings, particularly any comparisons between lead-free and lead wheel balancing weights in terms of price, ease of installation, durability, and other attributes of performance and suitability.

In assessing the usability of any data or information that may be submitted, EPA plans to follow the guidelines in EPA's "A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information" (EPA 100B-03/001), referred to as the "Assessment Factors Document." The "Assessment Factors Document" was published in the **Federal Register** issue of July 1, 2003 (68 FR 39086) (FRL-7520-2) and is available on-line at <http://www.epa.gov/osa/spc/assess.htm>.

#### List of Subjects

Environmental protection, lead, wheel balancing weights, zinc.

Dated: July 6, 2009.

**James Jones,**

*Acting Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.*

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## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2007-0837; FRL-8425-3]

### Malathion; Product Cancellation Order and Amendments to Terminate Uses

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

**ACTION:** Notice.

**SUMMARY:** This notice announces EPA's order for the cancellations and amendments to terminate uses, voluntarily requested by the registrants and accepted by the Agency, of products containing the pesticide malathion, pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. This cancellation order follows a May 20, 2009 **Federal Register** Notice of Receipt of Requests from the malathion registrants to voluntarily cancel or to amend to terminate uses of certain malathion product registrations. These are not the last malathion products registered for use in the United States. In the May 20, 2009 Notice, EPA indicated that it would issue an order implementing the cancellations and amendments to terminate uses, unless the Agency received substantive comments within the 30 day comment period that would merit its further review of these requests, or unless the registrants withdrew their requests within this period. The Agency did not receive any comments on the notice. Further, the registrants did not withdraw their requests. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested cancellations and amendments to terminate uses. Any distribution, sale, or use of the malathion products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

**DATES:** The cancellations are effective July 15, 2009.

**FOR FURTHER INFORMATION CONTACT:** Eric Miederhoff, Special Review and Reregistration Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-

0001; telephone number: (703) 347-8028; fax number: (703) 308-7070; e-mail address: [miederhoff.eric@epa.gov](mailto:miederhoff.eric@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

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

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. 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 a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0837. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility 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>.

##### II. What Action is the Agency Taking?

This notice announces the cancellations and amendments to terminate uses, as requested by registrants, of certain end-use malathion products registered under section 3 of FIFRA. These registrations are listed in sequence by registration number in Tables 1 and 2 of this unit.

TABLE 1.—MALATHION PRODUCT CANCELLATIONS

Registration Number	Product Name	Company
228-68	Riverdale Malathion 5	Nufarm Americas, Inc.
228-93	Riverdale Bin Spray	Nufarm Americas, Inc.