



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2011-0961; FRL-9332-2]

Results from Inert Ingredient Test Orders Issued under EPA's Endocrine Disruptor Screening Program: New Data Compensation Claims; Potential Disapproval of Inert Uses Pending Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In January and February of 2010, EPA issued test orders (Data Call-Ins) to companies that manufacture or import any of the following nine chemicals currently used as inert ingredients in pesticide products: Acetone, isophorone, di-sec-octyl phthalate, toluene, methyl ethyl ketone, butyl benzyl phthalate, dibutyl phthalate, diethyl phthalate, and dimethyl phthalate. The test orders required recipients to submit specific screening data on hormonal effects under EPA's Endocrine Disruptor Screening Program (EDSP) and the Federal Food, Drug, and Cosmetic Act (FFDCA). In response to the test orders, companies have agreed to develop data and have asserted data compensation rights for two inert ingredients, acetone and isophorone. No companies are developing data for the remaining seven inert ingredients. For di-sec-octyl phthalate and toluene, EPA plans to issue new test orders as both chemicals meet the selection criteria for endocrine testing under the Safe Drinking Water Act (SDWA). EPA has no plans to issue further test orders for methyl ethyl ketone, butyl benzyl phthalate, dibutyl phthalate, diethyl phthalate, and dimethyl phthalate, but plans to no longer approve their use as inert ingredients in pesticide products. EPA is, however, offering an opportunity for interested parties to comment or commit to submitting the required data.

DATES: Comments must be received on or before [*insert date 60 days after date of publication in the Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2011-0961, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2011-0961. 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 or e-mail. The 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.

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, is not placed on the Internet and will be publicly available only in hard copy form. 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 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.

FOR FURTHER INFORMATION CONTACT: Anthony Britten, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8179; fax number: (703) 605-0781; e-mail address: Britten.Anthony@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; or if you manufacture or import chemical substances that are used in pesticides. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).
- Chemical manufacturers, importers and processors (NAICS code 325).
- Pesticide, fertilizer, and other agricultural chemical manufacturing (NAICS code 3253).
- Scientific research and development services (NAICS code 5417), e.g., persons who conduct testing of chemical substances for endocrine effects.

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

1. *Submitting CBI.* Do not submit this information to EPA through 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 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:
- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
 - ii. 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.
 - iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
 - iv. Describe any assumptions and provide any technical information and/or data that you used.
 - v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

EPA began issuing test orders (Data Call-Ins) on January 14, 2010, to companies that manufacture or import the following pesticide inert ingredients: Acetone, isophorone, di-sec-octyl phthalate, toluene, methyl ethyl ketone, butyl benzyl phthalate, dibutyl phthalate, diethyl phthalate, and dimethyl phthalate. These inert ingredients were selected for initial testing based solely on their potential for broad public exposure. The test orders required recipients to generate data that would allow the Agency to screen these chemicals for their potential to interact with the estrogen, androgen or thyroid hormonal systems. Extensive background on the Agency's endocrine program is available at <http://www.epa.gov/endo>.

Based on responses to the test orders, EPA is announcing that consortia are developing data for two of these inert ingredients, acetone and isophorone, and have asserted data compensation rights. EPA has determined that the data protection rights as given in FIFRA section 3(c)(1)(F) and FFDCA 408(i) apply for all data submitted in support of the EDSP test orders. The other inert ingredients that were subject to EDSP test orders are unsupported; no one is developing required data. EPA plans to issue new test orders for di-sec-octyl phthalate and toluene under the Safe Drinking Water Act

(SDWA) because the chemicals meet the selection criteria. EPA has no plans to issue further test orders for the remaining five inert ingredients (methyl ethyl ketone, butyl benzyl phthalate, dibutyl phthalate, diethyl phthalate, and dimethyl phthalate), but plans to stop approving their use in pesticide products as inert ingredients on a timeline described later in this notice. EPA is, however, offering an opportunity for interested parties to comment or commit to submitting the required data.

The following table lists the inert ingredients subject to EDSP test orders by chemical name and Chemical Abstract Service Registry Number (CAS Reg. No.), and identifies whether consortia are generating data or EPA is issuing new test orders. For information on which companies received test orders and their individual responses, see http://www.epa.gov/scipoly/oscpendo/pubs/edsp_orders_status.pdf.

Table of Inert Ingredients Subject to EDSP Test Orders for Tier 1 Screening Data

Inert Ingredients Subject to Test Orders: Chemical Name and CAS Reg. No.	Date Test Orders Issued	Are consortia generating data, or will EPA issue new test orders under SDWA?
Acetone (67-64-1)	2/4/2010	Consortium is developing data
Butyl benzyl phthalate (85-68-7)	1/21/2010	No
Dibutyl phthalate (84-74-2)	1/21/2010	No
Diethyl phthalate (84-66-2)	1/21/2010	No
Dimethyl phthalate (131-11-3)	1/21/2010	No
Di-sec-octyl phthalate (117-81-7)	1/21/2010	New test orders planned
Isophorone (78-59-1)	1/14/2010	Consortium is developing data
Methyl ethyl ketone (78-93-3)	1/28/2010	No
Toluene (108-88-3)	2/25/2010	New test orders planned

The following list identifies the screening data that EPA required in the test orders for potential effects on the thyroid, estrogen and androgen systems, and the estimated number of months needed to develop the data. If screening data were to identify

endocrine activity, additional testing might be required to establish dose-levels for adverse effects.

Required Tier 1 Endocrine Screening Data and Estimated Time (Months) to Develop

Amphibian Metamorphosis (Frog): 15

Androgen Receptor Binding (Rat Prostate): 6

Aromatase (Human Recombinant): 6

Estrogen Receptor Binding : 6

Estrogen Receptor Transcriptional Activation (Human Cell Line (HeLa-9903)): 6

Fish Short-term Reproduction: 12

Hershberger (Rat): 9

Female Pubertal (Rat): 15

Male Pubertal (Rat): 15

Steroidogenesis (Human Cell Line - H295R): 6

Uterotrophic (Rat): 9

EPA has included a sample test order in the docket for reference. If after reading this notice and the test order requirements, you intend to submit data, indicate this clearly in your comments.

1. Supported inert ingredients subject to data compensation. Company consortia for isophorone (CAS Reg. No. 78-59-1) and acetone (CAS Reg. No. 67-64-1) are conducting all eleven Tier 1 endocrine assays to screen for potential effects on the thyroid, estrogen and androgen systems. These data are due January 21, 2012, for isophorone and February 7, 2013, for acetone. Data protection rights as given in FIFRA section 3(c)(1)(F) and FFDCA 408(i) apply for all data submitted in support of the EDSP

test orders. Registrants of products containing acetone or isophorone must identify the source of these chemicals on their Confidential Statements of Formula (CSF). If a CSF lists a source of isophorone or acetone other than a consortia member, EPA intends to take appropriate action to ensure that the registrant takes one of the following actions: (i) Changes the source to a consortia member; (ii) submits proof of an offer to pay the consortia to use their data; (iii) submits a commitment to generate the required data; (iv) reformulates; or (v) cancels. If necessary, EPA will issue a Data Call-In or a product-specific test order to ensure one of these actions is taken. A **Federal Register** notice, “Endocrine Disruptor Screening Program; Policies and Procedures for Initial Screening,” (April 15, 2009, 74 FR 17559) (FRL-8399-9), addresses data compensation in more detail. <http://www.gpo.gov/fdsys/pkg/FR-2009-04-15/pdf/E9-8706.pdf>. The acetone and isophorone consortia are managed by and reachable through the American Chemistry Council (<http://www.americanchemistry.com>).

2. *Unsupported inert ingredients subject to new test orders.* EPA plans to issue new test orders for di-sec-octyl phthalate (CAS Reg. No. 117-81-7) and toluene (CAS Reg. No. 108-88-3) to require Tier 1 endocrine screening data because these chemicals also meet the criteria under SDWA. EPA plans to wait until the SDWA test orders are issued and the responses are received before taking further action on these two chemicals. For more information about SDWA test orders, see the **Federal Register** notice, “Endocrine Disruptor Screening Program; Draft Policies and Procedures for Screening Safe Drinking Water Act Chemicals” (November 17, 2010; 75 FR 70558) (FRL-8848-9). <http://www.gpo.gov/fdsys/pkg/FR-2010-11-17/pdf/2010-28812.pdf#page=1>.

3. *Unsupported inert ingredients subject to disapproval pending public comment.*

Importers and manufacturers of the following chemicals declined to develop data in response to test orders: Methyl ethyl ketone (CAS Reg. No. 78-93-3); butyl benzyl phthalate (CAS Reg. No. 85-68-7); dibutyl phthalate (CAS Reg. No. 84-74-2); diethyl phthalate (CAS Reg. No. 84-66-2); and dimethyl phthalate (CAS Reg. No. 131-11-3). Rather, all elected to “opt out” of the pesticide market rather than conduct testing, and, under the “opt-out” provision, were required to cease, within 6 months of EPA issuing the test order, all sales and distribution of their chemical for use in pesticide formulations.

EPA is not pursuing further test orders at this time for these chemicals. None meet the criteria for new test orders under SDWA, and dialogue with pesticide trade associations indicates that member companies are unlikely to develop data in response to further FFDCA test orders. Instead, EPA intends to no longer approve the use of these inert ingredients in pesticide registration applications or reformulations unless a commenter commits to submitting required data. The effective date for this action would be the same effective date that EPA has proposed for revoking the tolerance exemptions for methyl ethyl ketone and diethyl phthalate; that is, 6 months after the date EPA publishes the tolerance revocation final rule. You can find the proposed rule in this issue of the **Federal Register**. For products already in the marketplace, EPA intends to take appropriate action to ensure registrants either reformulate or cancel those products. If necessary, EPA will issue test orders (product-specific Data Call-Ins). EPA also is reminding registrants that current regulations require them to amend any pesticide product registrations before selling a pesticide product with a composition different from that listed on the approved Confidential Statement of Formula.

EPA believes its proposed timeline for no longer approving use of these chemicals as inert ingredients gives registrants sufficient time to take appropriate action. Under the EDSP test orders, the manufacturers and importers that “opted out” of testing had to cease all sales and distribution to the pesticide market within 6 months of EPA issuing the test order. EPA issued the last test orders for these chemicals on January 28, 2010, so all sales and distribution of methyl ethyl ketone, butyl benzyl phthalate, dibutyl phthalate, diethyl phthalate, and dimethyl phthalate for use in pesticide formulations were to have ceased as of July 28, 2010. EPA has also been performing outreach to trade groups to inform them about the potential loss of these chemicals as inert ingredients. This **Federal Register** document provides further notice.

To help companies avoid formulating new product with methyl ethyl ketone, butyl benzyl phthalate, dibutyl phthalate, diethyl phthalate, and dimethyl phthalate, EPA plans to remove them from its lists of approved inert ingredients. These lists, now consolidated in a web-searchable database called “InertFinder” (<http://www.epa.gov/pesticides/inertfinder>), are informational only. Adding or removing a chemical from these lists is not a regulatory action. InertFinder points users to the Code of Federal Regulations as the legal record for uses that require a tolerance or tolerance exemption for residues on raw agricultural commodities or processed food. For inert ingredient uses that do not require a tolerance or exemption (such as nonfood- only uses), InertFinder helps formulators find chemicals that EPA has previously approved for use as inert ingredients in pesticide products.

B. What is the Agency's Authority for taking this Action?

The statutory authority for the Endocrine Disruptor Screening Program is

described in detail in a companion document in this issue of the **Federal Register** which proposes to revoke the tolerance exemptions for methyl ethyl ketone and diethyl phthalate, and in a **Federal Register** notice titled, “Endocrine Disruptor Screening Program; Policies and Procedures for Initial Screening,” (74 FR 17560), <http://www.gpo.gov/fdsys/pkg/FR-2009-04-15/pdf/E9-8706.pdf>.

List of Subjects

Environmental protection, Endocrine disruptors, Pesticides and pests.

Dated : February 17, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2012-6164 Filed 03/13/2012 at 8:45 am; Publication Date: 03/14/2012]