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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0964; FRL-9332-3]

Revocation of Tolerance Exemptions for Diethyl Phthalate and Methyl Ethyl Ketone; No Data Being Developed as Required by Test Orders (Data Call-Ins) Under EPA's Endocrine Disruptor Screening Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes, under section 408(e)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA), to revoke the existing exemptions from the requirement of a tolerance (tolerance exemptions) for residues of diethyl phthalate and methyl ethyl ketone when used as inert ingredients in pesticide products because there are insufficient data to make the determination of safety required by FFDCA. No manufacturer or importer of these chemicals has committed to conduct testing and submit data required by test orders that EPA issued under the Endocrine Disruptor Screening Program (EDSP). 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-2011-0964, 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-2011-0964. 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, 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.

C. What Can I Do if I Wish EPA to Maintain a Tolerance or Tolerance Exemption that the Agency Proposes to Revoke?

This proposed rule provides a comment period of 60 days for any person to state an interest in retaining a tolerance exemption proposed for revocation. If EPA receives a comment within the 60-day period to that effect, EPA will not proceed to revoke the tolerance exemption immediately. However, EPA will take steps to ensure the submission of any needed supporting data and will either issue an order under sections 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and section 408(p)(5) of FFDCA if the commenter is a registrant or manufacturer, or will issue an order in the **Federal Register** under FFDCA section 408(f) if the interested party is neither a registrant nor manufacturer.

EPA issues a final rule after considering comments that are submitted in response to this proposed rule. Comments should be limited only to the inert ingredients and tolerance exemptions subject to this proposed rule. After considering comments, EPA will issue a final regulation determining whether revocation of the tolerance exemptions is appropriate and making a final finding on whether these tolerance exemptions are "safe" within the meaning of section 408(b)(2)(A)(ii).

In addition to submitting comments in response to this proposal, you may also submit an objection at the time of the final rule pursuant to section 408(g) (21 U.S.C. 346a(g)). If you anticipate that you may wish to file objections to the final rule, you must raise those issues in your comments on this proposal. EPA will treat as waived any issues raised in objections that could reasonably have been, but were not, presented in comments on this proposal. Similarly, if you fail to file an objection to the final rule

within the time period specified, you will have waived the right to raise any issues resolved in the final rule. After the specified time, issues resolved in the final rule cannot be raised again in any subsequent proceedings.

II. Background

A. What Action is the Agency Taking?

EPA, under section 408(e)(1) of FFDCA, is proposing to revoke tolerance exemptions for residues of diethyl phthalate and methyl ethyl ketone in or on raw agricultural commodities and processed foods when these chemicals are used as inert ingredients in pesticide products. These revocations would be effective 6 months after the final rule is published in the **Federal Register**.

EPA issued test orders to manufacturers and importers of diethyl phthalate and methyl ethyl ketone on January 21, 2010 and January 28, 2010, respectively. 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 consistent with EPA's Endocrine Disruptor Screening Program (EDSP), developed in accordance with section 408(p) of FFDCA.

Section 408(p)(3) of FFDCA requires screening of "all pesticide chemicals," including by definition inert ingredients in pesticide products, to determine their potential to disrupt the endocrine system. 21 U.S.C. 345a(p)(3). The statute also ties the availability of these or other data "on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects" to the safety finding that EPA must make in order to allow a tolerance or exemption to remain. 21 U.S.C. 346a(b)(2)(D).

No company which received a test order has committed to submit the required data to support the continued use of these chemicals as pesticide inert ingredients. 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's outreach to trade associations suggests that registrants of pesticide products will also decline to conduct required testing in order to continue using these chemicals as inert ingredients. EPA therefore is not issuing further test orders at this time. Rather, this proposed rule offers a final opportunity for any interested parties to commit to develop these data, which FFDCA makes necessary to support a tolerance or exemption. A companion notice in this issue of the **Federal Register** provides background on all the inert ingredient test orders issued and the responses EPA has received to date.

In sum, because no one has committed to generate these data, and because EPA has no other data on which it could rely to evaluate the endocrine disruption potential of these inert ingredients, EPA is proposing to revoke the tolerance exemption under 40 CFR 180.930 for diethyl phthalate and the tolerance exemption under 40 CFR 180.920 for methyl ethyl ketone. In the absence of any data bearing on the endocrine disruption potential of these chemicals, EPA cannot find that these chemicals continue to meet the required safety standard under FFDCA section 408(b)(2). Through this proposed rule, the Agency is inviting individuals who need these exemptions to identify themselves and the tolerance exemptions that are needed. If during the comment period for this proposal no one either submits or commits to generate data required by the test orders, EPA will

revoke these tolerance exemptions. The following list identifies the data EPA required in the test orders to screen for potential effects on the thyroid, estrogen and androgen systems, and the estimated time to generate the data. If screening data were to identify endocrine activity, additional testing might be required to establish dose-levels for adverse effects.

Required Data and Estimated Number of 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 loaded a sample test order in the docket for reference. If after reading this proposed rule and the test order requirements, you intend to submit data, indicate this clearly in your comments.

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

This proposed rule is issued pursuant to section 408(e)(1)(B) of FFDCA (21 U.S.C. 346a(e)(1)(B)). A "tolerance" represents the maximum level for residues of

pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Section 408 of FFDCA, 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA), Public Law 104-170, authorizes the establishment of tolerances, exemptions from tolerance requirements, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Without a tolerance or exemption, food containing pesticide residues is considered to be unsafe and therefore "adulterated" under section 402(a) of FFDCA, 21 U.S.C. 342(a). Such food may not be distributed in interstate commerce (21 U.S.C. 331(a)).

Section 408(b)(2)(A)(i) of the FFDCA requires EPA to modify or revoke a tolerance if EPA determines that the tolerance is not "safe." 21 U.S.C. 346a(b)(2)(A)(ii). Section 408(b)(2)(A)(ii) of the FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." Among those factors that EPA is directed to consider in establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue is "such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects; . . . ." 21 U.S.C. 346a(b)(2)(D)(viii).

FFDCA section 408(p)(1) requires EPA "to develop a screening program, using appropriate validated test systems and other scientifically relevant information to determine whether certain substances may have an effect in humans that is similar to an

effect produced by a naturally occurring estrogen, or such other effects as [EPA] may designate." 21 U.S.C. 346a(p). FFDCA section 408(p)(3) expressly requires that EPA "shall provide for the testing of all pesticide chemicals." FFDCA section 201 defines "pesticide chemical" as "any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), including all active and pesticide inert ingredients of such pesticide." 21 U.S.C. 231(q)(1). FFDCA section 408(e)(1)(B) provides that the Administrator may issue a regulation "establishing, modifying, suspending under section (l)(3), or revoking an exemption of a pesticide chemical residue from the requirement of a tolerance." 21 U.S.C. 346a(e)(1)(B).

C. When Would this Action Become Effective?

EPA is proposing to revoke the tolerance exemptions for diethyl phthalate and methyl ethyl ketone effective 6 months after the date the final rule publishes in the **Federal Register**. EPA believes its proposed timeline gives registrants sufficient time to take appropriate action. Under the EDSP test orders, manufacturers and importers that "opted out" of testing had to cease all sales and distribution of the chemical to the pesticide market for use in formulating pesticide products 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 diethyl phthalate and methyl ethyl ketone for use in formulating pesticide products 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.

Any commodities treated with pesticide products containing the inert ingredients diethyl phthalate and methyl ethyl ketone and in the channels of trade following the

tolerance revocations, shall be subject to FFDCA section 408(1)(5), as established by FQPA. Under this section, any residues of these pesticide chemicals in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of FDA that:

i. The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA.

ii. The residue does not exceed the level that was authorized, at the time of the application or use, to be present on the food under a tolerance or exemption from a tolerance. Evidence to show that food was lawfully treated may include records that verify the dates when the pesticide was applied to such food.

III. Statutory and Executive Order Reviews

EPA is proposing to revoke the exemptions from the requirement of a tolerance for diethyl phthalate and methyl ethyl ketone. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This proposed rule does not contain any information collections subject to OMB approval under the *Paperwork Reduction Act* (PRA), 44 U.S.C. 3501 *et seq*., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the *Unfunded Mandates Reform Act of 1995* (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority*

Populations and Low-Income Populations (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this proposed rule, do not require the issuance of a proposed rule, the requirements of the *Regulatory Flexibility Act* (RFA) (5 U.S.C. 601 *et seq*.) do not apply. The Agency hereby certifies that this proposed action will not have a significant negative economic impact on a substantial number of small entities. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States.

This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this proposed rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000). Executive Order 13175 requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Endocrine disruptors, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 17, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 180--[AMENDED]

1. The authority citation for 40 CFR part **180** continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

§ 180.920 [Amended]

2. In §180.920, the table is amended by removing the entire entry for "Methyl ethyl ketone."

§ 180.930 [Amended]

3. In §180.930, the table is amended by removing the entire entry for "Diethylphthalate."

[FR Doc. 2012-6210 Filed 03/13/2012 at 8:45 am; Publication Date: 03/14/2012]