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**Instructions:** Direct your comments to Docket ID No. EPA-HQ-ORD-2010-0991. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked "late," and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at <http://www.regulations.gov>, including any personal information provided, unless a 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 <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site 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 <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public 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:** Documents in the docket are listed in the <http://www.regulations.gov> index. 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 materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

Dated: December 2, 2010.

**Darrell A. Winner,**

*Acting Director, National Center for Environmental Assessment.*

[FR Doc. 2010-30848 Filed 12-7-10; 8:45 am]

**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2010-0548; FRL-8852-8]

### Petition for a Ban on Triclosan; Notice of Availability

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

**ACTION:** Notice.

**SUMMARY:** This notice makes available for review and public comment a petition submitted by Beyond Pesticides, and Food & Water Watch (hereafter referred to as "the petitioners") to the Environmental Protection Agency (hereafter referred to as "EPA" or "the Agency"), asking EPA to use its authority under various statutes to regulate triclosan. Triclosan is an antimicrobial substance used in pesticide products, hand sanitizers, toothpaste, and other consumer products. The petitioners claim that the "pervasive and widespread use" of triclosan poses significant risks to human health and the environment. In addition, the petitioners claim that the agency failed to address the impacts posed by triclosan's degradation products on human health and the environment, failed to conduct separate assessments for triclosan residues in contaminated drinking water and food, and is complacent in seriously addressing concerns related to antibacterial resistance and endocrine disruption. EPA has established a public docket, which contains a copy of the petition and will contain all comments received in response to this notice. The docket may be accessed as described in this notice.

**DATES:** Comments must be received on or before February 7, 2011.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2010-0548, 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-2010-0548. When commenting, please specify the statute to which your comments refer (FIFRA, FFDCA, SDWA, CWA, or ESA) and the specific issue(s) raised in the petition regarding that statute on which you are commenting. EPA's policy is that all comments received will be included in the docket without change and may be made available online 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 [www.regulations.gov](http://www.regulations.gov) or e-mail. The [www.regulations.gov](http://www.regulations.gov) Web site 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 [www.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:** Timothy F. McMahon, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-6342; fax number: (703) 308-8481; e-mail address: [mcmahon.tim@epa.gov](mailto:mcmahon.tim@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 a business engaged in the manufacturing of pesticides and other agricultural chemicals. Potentially affected entities may include, but are not limited to:

- Pesticide and other agricultural and chemical manufacturing (NAICS 325320) e.g., businesses engaged in the manufacture of pesticides.
- Pulp and paperboard industries (NAICS 322110 and 322130).
- Antimicrobial pesticides (NAICS 32561).

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 [www.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 as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed 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 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.

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.

3. **Environmental justice.** EPA defines Environmental Justice as the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may bear disproportionate adverse impacts from exposure to the

pesticide discussed in this document, compared to the general population.

**II. What action is the Agency taking?**

Through this notice, the Agency is making the petition and other correspondence submitted by Beyond Pesticides, and Food & Water Watch available for public review and comment. Any public comments received on this petition will be included in the electronic docket and reviewed by the Agency. Following review of the petition and any comments received in response to this notice, EPA will issue its decision and response to the petition.

Triclosan is an antimicrobial active ingredient that is contained in a variety of bacteriostats, fungistats, mildewstats, and deodorizer products. There are currently 20 antimicrobial registrations, which EPA regulates under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). There are also consumer uses of triclosan, such as its use in soaps and cleansers that are regulated by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FFDCA).

In 2008, EPA completed a Reregistration Eligibility Decision (RED) document for triclosan. This RED document described the conclusions of EPA's comprehensive review of the potential risks to human health and the environment resulting from the registered pesticidal uses of triclosan. In conducting the review for the RED, EPA considered all available data on triclosan, including data on endocrine effects, developmental and reproductive toxicity, chronic toxicity, and carcinogenicity. The 2008 EPA assessment also relied in part on 2003-2004 biomonitoring data available from the National Health and Nutrition Examination Survey (NHANES) which reported measurements of urinary concentrations of triclosan in the U.S. population. Therefore, the 2008 EPA assessment was inclusive of all triclosan-related exposures (i.e., EPA and FDA regulated uses).

The 2008 RED also considered new research data on the thyroid effects of triclosan in laboratory animals made available through the EPA's Office of Research and Development (ORD). Since the 2008 assessment, additional data on effects of triclosan on estrogen have also been made available from ORD. The ORD studies on the thyroid and estrogen effects led EPA to determine that additional research on the potential health consequences of endocrine effects of triclosan is warranted. This research is underway and will help characterize the human

relevance and potential risk of the results observed from initial laboratory animal studies. In addition, EPA will be updating the assessment of triclosan exposure in the 2008 RED using the newly released 2005–2006 NHANES urinary monitoring results. The Agency will pay close attention to this ongoing research and will amend the regulatory decision if the science supports such a change. Also, the Agency has previously indicated that because of the amount of research being planned and currently in progress, it will undertake another comprehensive review of triclosan beginning in 2013.

Triclosan is also recognized as an emerging contaminant of concern by EPA's Office of Water. Through its authority under the Clean Water Act, EPA is conducting an effects assessment for triclosan that may be used by States and authorized Tribes to establish water quality standards for triclosan.

Under the Safe Drinking Water Act, EPA evaluated triclosan for inclusion on the third contaminant candidate list (CCL 3). The CCL 3 was published on October 8, 2009 (74 FR 51850) and includes contaminants that are currently unregulated in drinking water, that are known or anticipated to occur in public water systems, and which may require regulation under the Safe Drinking Water Act. EPA developed the CCL 3 using a multi-step process recommended by the National Academies of Science and the National Drinking Water Advisory Council. EPA considered the best available occurrence and health effects data to evaluate a universe of approximately 7,500 contaminants, from which EPA identified the list of 116 contaminants that present the greatest public health concern in drinking water. Triclosan was included in the universe of contaminants evaluated. However, EPA determined triclosan did not present as great a public health concern in drinking water as the contaminants that were selected for the CCL 3 list.

A related petition was filed with FDA by the same organizations that filed the EPA petition. The Agency is also aware of FDA's ongoing effort to finalize the topical antimicrobial over-the-counter (OTC) drug monograph under which some products containing triclosan are regulated. EPA and FDA intend to collaborate and share information throughout the public comment and petition response process as well as FDA's ongoing rule development.

### III. Summary of the Petition

The Agency received a petition from Beyond Pesticides, and Food & Water Watch on January 28, 2010 that seeks

relief under several regulatory statutes. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), the petitioners ask EPA to act to cancel and suspend the registration of pesticides containing triclosan. Under the Clean Water Act (CWA), the petitioners request that the Administrator impose technology-based effluent limitations, health-based toxic pollutant water quality pretreatment requirements, and biosolids regulation for triclosan. Under the Safe Drinking Water Act (SDWA), the petitioners request that the Administrator conduct a comprehensive assessment of the appropriateness of regulating triclosan under SDWA. Under the Endangered Species Act (ESA), the petitioners request that the Administrator comply fully with ESA, including consultation and biological assessment requirements. EPA has established a public docket, which contains a copy of the petition and will contain all comments received in response to this Notice. The docket may be accessed as described in this Notice. The statutes mentioned and the specific relief requested under each statute is summarized as follows:

- *FIFRA*. The petition states that "The hazards associated with Triclosan use and exposure during the pendency of a long review does not meet EPA's statutory duty to protect health and the environment. That is, because scientific studies demonstrate that the substance is used so pervasively that it is present in most people's bodies, EPA must take the most protective steps provided for under the statute to protect public health. In this regard, petitioners request that EPA (1) issue a notice of cancellation of the registrations of all products containing triclosan, pursuant to 7 U.S.C. 136d(b)(1), and (2) at the same time issue an emergency order pursuant to 7 U.S.C. 136d(c)(3) to suspend immediately those registrations."

- *Clean Water Act*. The petition states that "numerous studies, including those of EPA, have established the substantial presence, and therefore serious threat, of triclosan to human health and the environment through the means of pollution of the nation's navigable waters. EPA's failures in this regard, in petitioners' view, are "arbitrary, capricious," and otherwise "not in accordance with law." Therefore, the Administrator should use her authority under the Act to evaluate these health and environmental effects thoroughly and act decisively, based on the abundance of scientific evidence and the express requirements of the CWA, to require proper regulation of triclosan.

She should use her authority to impose technology-based effluent limitations, health-based pollutant water quality pretreatment requirements, and biosolids regulation.

- *Safe Drinking Water Act*. The petition states that "EPA's reregistration decision sets the stage for a violation of the SWDA, in that triclosan would be allowed to contaminate drinking water at levels that threaten human health and the environment. For this reason, petitioners request that the Administrator conduct a comprehensive assessment of the appropriateness of regulating triclosan under the SDWA."

- *Endangered Species Act*. The petition states that "because triclosan is present in the large environment, EPA's registration of that substance creates potential jeopardy for listed threatened and endangered species and may destroy or adversely modify designated critical habitats. This presence has been abundantly demonstrated throughout this petition. Accordingly, Petitioners request that the Administrator comply fully with the ESA, including the consultation and biological assessment requirements. Petitioners note, in this regard, that notwithstanding FIFRA's primary rule in regulating pesticides, courts have held that EPA must comply with ESA in its administration of FIFRA."

### List of Subjects

Environmental protection, Antimicrobials, triclosan, Pesticides and pests.

Dated: December 2, 2010.

**Joan Harrigan-Farrelly,**  
Director, Antimicrobials Division, Office of Pesticide Programs.

[FR Doc. 2010-30850 Filed 12-7-10; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2010-0008; FRL-8852-5]

### Pesticide Products; Registration Applications

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

**ACTION:** Notice.

**SUMMARY:** This notice announces receipt of applications to register new uses for pesticide products containing currently registered active ingredients, pursuant to the provisions of section 3(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. EPA is publishing this Notice of such applications, pursuant to section 3(c)(4) of FIFRA.