UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

5/13/15

Subject: Response to Citizen Petition for a Ban on Triclosan

This letter constitutes the U.S. Environmental Protection Agency's ("EPA" or "the agency") response to the Citizen Petition for a Ban on Triclosan dated January 14, 2010 ("petition"), submitted by Food & Water Watch and Beyond Pesticides seeking a ban on the antimicrobial pesticide triclosan. This letter also constitutes the agency's response to the comments received during the public comment period on the petition.

The petition specifically requests that the agency take the following steps under each of the following statutes:

> Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Food, Drug, and Cosmetic Act (FFDCA): (1) reopen the Reregistration Eligibility Decision (RED); (2) issue a notice of cancellation of the registrations of all products containing triclosan; and (3) concurrently issue an emergency order to immediately suspend the existing triclosan registrations.
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> Clean Water Act (CWA): (1) impose technology-based effluent limitations; (2) establish health-based toxic pollutant water quality pretreatment requirements; and (3) impose biosolids regulation for triclosan.
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> Safe Drinking Water Act (SDWA): conduct a comprehensive assessment of the appropriateness of regulating triclosan under SDWA.
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> Endangered Species Act (ESA): (1) conduct a biological assessment; and (2) engage in consultation with the Secretary of the Interior and the Secretary of Commerce.

On December 10, 2010, the EPA published a Notice in the Federal Register (FR) announcing the availability of the petition for a 60-day public comment period. The petition was made available for comment at regulations.gov in docket EPA-HQ-OPP-2010-0548. After extending the comment period for an additional 60 days, the comment period closed on April 8, 2011. During the public comment period, the agency received approximately 785 individual submissions. Within those submissions, several organized groups submitted letters with multiple signatures and comments. These submissions to the agency included 48,883 letters or signatures in support of the ban on triclosan and 4,265 signatures in support of allowing the continued registration of triclosan.

Summary of Agency Response to the Petition

After carefully considering the information presented in the petition and submitted by commenters, the EPA determined that the information available at this time does not support granting the majority of the relief requested. The agency notes, however, that it is currently engaged across various programs in assessing the risks posed by triclosan, such as the risk assessment process in the registration review program, which includes a comprehensive review of human health and ecological risks (under FIFRA), and the risk assessment process for biosolids (under CWA). Depending on the results of these assessments, the EPA may consider regulatory action. To the extent that the petitioners are seeking regulatory actions in advance of scheduled review and risk assessment processes, the EPA does not plan to take any actions before its analyses have been completed. Accordingly, EPA is denying the petition's requests to reopen the RED, issue a notice of cancellation of the registrations of all products containing triclosan, and issue an emergency order suspending existing triclosan registrations under FIFRA. The EPA is also denying the petition's requests to impose new technology-based effluent limitations for triclosan, to establish water quality pretreatment requirements for triclosan, and to impose biosolids regulation for triclosan under the CWA. Finally, because the EPA had already planned to carry out a comprehensive ecological risk assessment that will evaluate the potential for effects on listed species, the EPA is granting the request to conduct a biological assessment under the ESA.

The EPA is neither granting nor denying the petition's request to conduct a comprehensive assessment of the appropriateness of regulating triclosan under the SDWA because the agency is already engaged in such an assessment. No further action is necessary to respond to petitioners' SDWA request.

Consideration of the Petition and Detailed Response

This response addresses both the information contained within the petition and the comments received during the 120-day public comment period. Most of the comments received were submitted in support of the petition and cite reasoning aligned with the assertions contained in the petition. The agency also received multiple comments in support of the continued registration of triclosan and denial of the petition. The petition and all comments can be viewed in full at regulations.gov in docket EPA-HQ-OPP-2010-0548.

Petitioners and some commenters have made the following assertions, among others, regarding triclosan:

(1) The ubiquity of triclosan results in endocrine disruption;
(2) The ubiquity of triclosan contributes to bacterial resistance in antibiotic medications and antibacterial cleansers;
(3) Triclosan is bioaccumulative and poses an immense body burden;
(4) Triclosan is not completely removed from wastewater and sludge, which may result in food contamination;
(5) The EPA's RED determination failed to address major degradates;
(6) Triclosan is highly toxic to various forms of algae and this can cause ecological damage; and
(7) Triclosan fails to provide the benefits claimed on product labels due to bacterial resistance, and is therefore misbranded in violation of the FFDCA.

Commenters that supported continued registration of triclosan under FIFRA and opposed regulation of triclosan under the CWA or the SDWA made the following assertions, among others:

(1) Triclosan is not a cause of endocrine related effects to humans or aquatic organisms at environmentally relevant concentrations;
(2) In situ studies on the impact of triclosan on bacterial resistance demonstrate no association between triclosan exposure and microbial resistance;
(3) Triclosan is not bioaccumulative and its presence in the body does not indicate that triclosan is causing harm;
(4) Triclosan is largely removed from wastewater and sludge, and does not result in food contamination;
(5) Triclosan does not pose a risk of harm to algae or cause ecological damage; and
(6) Triclosan should not be addressed through CWA because publicly owned treatment works (POTWs) would bear the cost of compliance with CWA regulations, not chemical manufacturers.

The first section of this response discusses the applicable statutory framework. The second section discusses triclosan's regulatory history and background. The third section sets out the EPA's responses to petitioners' arguments in favor of the actions they seek under the FIFRA, the FFDCA, the CWA, the SDWA, and the ESA. The final section provides the EPA's findings and conclusions on the petition.

I. Legal Framework

A. *FIFRA and ESA*

Subject to limited exceptions, a pesticide may be distributed or sold in the United States only if it is registered by the EPA under FIFRA § 3(a), 7 U.S.C. § 136a(a). Under FIFRA, the EPA must register a pesticide if, among other things, the pesticide, when used in accordance with widespread and commonly recognized practice, generally will not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). Section 2(bb) defines "unreasonable adverse effects on the environment" as, among other things, "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide . . . ." 7 U.S.C. § 136(bb)(1).[1] This "risk-benefit" standard requires the EPA to compare the risks presented from the use of a pesticide with the benefits to society from the use of the pesticide. Once a pesticide is registered, the EPA must periodically review that pesticide registration 7 U.S.C. §§ 136a(g), 136a-1.

If the EPA determines at any time that a registered pesticide, including its approved labeling, no longer meets the standard for registration, the EPA may initiate cancellation proceedings. 7 U.S.C. § 136d(b). To do this, the agency must: a) prepare a notice of intent to cancel the registration (NOIC) that states the reasons for the EPA's proposed decision; b) consult the Secretary of Agriculture, the Scientific Advisory Panel, and the Secretary of Human Health and Services (when a public health use is affected) for their comments on the NOIC; and c) address any comments from those parties. Under the statute's procedures, the EPA must then send the NOIC to the registrant and publish it in the Federal Register. Within 30 days of receiving the NOIC, a registrant (or another adversely affected person) can request a hearing to present evidence against cancellation. After such a hearing, the agency may issue an order canceling the registration, require modifications to the label or packaging, or withdraw the initial notice. If no hearing is requested, then the NOIC becomes final and effective 30 days after the date of the

[1] The definition of the term in FIFRA section 2(bb) also includes "(2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21" (section 408 of the Federal Food, Drug, and Cosmetic Act). However, the petition did not include any assertions regarding a human dietary risk from residues from use of triclosan pesticides in or on food.

registrant's receipt of the NOIC or the date of publication in the Federal Register, whichever is later, 7 U.S.C. § 136d(b).

The EPA may also commence proceedings to suspend the registration of a pesticide during the period necessary to complete cancellation proceedings if it determines that an "imminent hazard" exists from the use of the pesticide. 7 U.S.C. § 136d (c). Section 2(l) of FIFRA defines imminent hazard as,

> [A] situation which exists when the continued use of a pesticide during the time required for [a] cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary pursuant to the Endangered Species Act . . . .

If the EPA determines that an emergency exists such that the imminent hazard will occur during the period necessary to complete normal suspension proceedings (including issuance of a NOIC), the EPA may issue an immediately effective emergency suspension order in advance of completing suspension proceedings. 7 U.S.C. § 136d(c)(3). Suspension (including an emergency suspension order) under FIFRA is an interim remedy that can remain in effect only for the duration of a cancellation proceeding; if the Administrator determines that initiation of a cancellation proceeding is not appropriate, suspension is no longer an option under FIFRA section 6.

In addition, section 3(g) of FIFRA requires the EPA to periodically review the registrations of all pesticides. The EPA has promulgated regulations to implement this requirement at 40 C.F.R. part 155. The registration review program makes sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no "unreasonable adverse effects on the environment." The EPA initiates a registration review by establishing a docket for a pesticide registration review case and opening the docket for public review and comment. Each docket contains information on what the agency knows about the pesticide and describes the anticipated data and assessment needs identified by the agency. The regulations outline subsequent phases of the registration review process and the associated opportunities for public comment.

Finally, section 7 of the ESA, 16 U.S.C. § 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they intend to take an "action" that may affect listed (*i.e.*, endangered or threatened) species or their designated critical habitat. Under the Act, the EPA is required to ensure actions are not likely to jeopardize the continued existence of a listed species, or result in the destruction or adverse modification of designated critical habitat.

B. *Clean Water Act (CWA)*

The Federal Water Pollution Control Act (33 U.S.C. §1251 et seq.), also known as the Clean Water Act (CWA), is the primary, statutory basis for protecting the Nation's waters. The Act's main ways to protect waters are by regulating discharges of pollutants into the waters of the United States through both technology-based and wáter quality-based effluent limitations. As set forth in Section 101(a), the CWA's objective is to restore and maintain the chemical, physical, and biological integrity of the Nation's waters, including the elimination of the discharge of pollution into the navigable waters, the setting of interim water quality standards providing protection and propagation of fish, shellfish, and wildlife, and the prohibition of the discharge of toxic pollutants in toxic amounts (33 U.S.C. §1251(a)(1),(2),(3)).

C. *Safe Drinking Water Act (SDWA)*

The Safe Drinking Water Act (SDWA, 42 U.S.C. § 300f-300j-26) authorizes the EPA to set national standards for drinking water to protect against both naturally-occurring and man-made contaminants that may be found in drinking water. Section 1412(b)(1) of the SDWA, as amended in 1996, requires EPA to publish a Contaminant Candidate List (CCL) every five years. The SDWA specifies that the list include contaminants that are not subject to any proposed or promulgated National Primary Drinking Water Regulations (NPDWRs), are known or anticipated to occur in public water systems, and may require regulation under the SDWA. For each CCL, EPA publishes a draft list and takes comment prior to issuing the final list. SDWA Section 1412(b)(1)(B)(ii) also requires EPA to make determinations of whether or not to regulate no fewer than five contaminants from the CCL every five years based upon three statutory criteria. EPA publishes preliminary determinations and takes comment prior to making final determinations. If EPA determines that these three statutory criteria are met and makes a final determination to regulate a contaminant, the agency has 24 months to publish a proposed Maximum Contaminant Level Goal (MCLG) and NPDWR. EPA sets the MCLG at the level at which no known or anticipated effects on the health of persons occur and which allows an adequate margin of safety. EPA typically establishes a Maximum Contaminant Level (MCL) as the enforceable NPDWR. After considering costs and benefits, EPA generally sets the MCL as close as feasible to the MCLG. After the proposal, the agency has 18 months, with the option of a nine month extension, to publish a final MCLG and NPDWR. EPA can enforce the NPDWRs by sending notice to state and public water systems, issuing administrative orders, or taking civil action.

II. Regulatory History and Background for Pesticides that Contain Triclosan

Triclosan (2,4,4' –trichloro-2'-hydroxydiphenyl ether) (PC Code 054901) was first registered with the EPA as an antimicrobial pesticide in 1969. Triclosan is currently registered under FIFRA as a bacteriostat, fungistat, and mildewstat for use as a materials preservative in residential, public access, commercial, institutional and industrial premises.

The EPA issued a Reregistration Eligibility Decision (RED) for triclosan in 2008. As part of that process, the Office of Pesticide Programs (OPP) performed a comprehensive assessment of the hazards, exposures and risks to human health and the environment resulting from the registered pesticidal uses of triclosan. All currently registered pesticidal uses of triclosan were found eligible for reregistration in 2008.

FIFRA does not require, or otherwise directly address, aggregating exposure to other potential sources of a pesticide in the context of determining whether the use of a non-dietary pesticide will cause unreasonable adverse effects on human health. In the case of triclosan, population-based biological monitoring data were available to assess the co-occurrence of uses, and EPA developed an aggregate exposure risk assessment for post-application residential exposures to triclosan for the 2008 RED. The best available data to perform an aggregate assessment at that time was the National Health and Nutrition Examination Survey (NHANES) biological monitoring data collected by the Centers for Disease Control and Prevention (CDC). NHANES is a program designed to assess the health and nutritional status of adults and children greater than six years old in the United States by examining a nationally representative sample of about 5,000 persons each year.[2] To capture children younger than six years old, exposure estimates for infants less than one year old were also included in the aggregate. Due to the nature of the samples and data collected in the NHANES program, the aggregate risk assessment

[2] http://www.cdc.gov/nchs/nhanes/about_nhanes.htm

took all sources of exposure to triclosan into account, including both the EPA-registered antimicrobial uses and the Food and Drug Administration (FDA)-regulated uses such as triclosan-containing toothpaste, hand soaps, and deodorants. Based on available data at that time, the agency concluded that total exposure to triclosan from all sources did not present risks of concern for human health.

The agency conducted a qualitative environmental risk assessment as part of the RED using existing ecotoxicity studies, United States Geological Survey monitored levels of triclosan found in waterways, and consumer environmental modeling. The agency determined that estimated concentrations of triclosan in surface water, when adjusted to represent contributions from pesticidal uses only, did not exceed levels of concern for acute risk, and that chronic risk was unlikely because of the low probability of triclosan being released into household wastewater and surface waters from either antimicrobial uses of triclosan pesticides or consumer uses of triclosan-treated plastics and textiles. The agency issued a post-RED Data Call-In (DCI) requiring monitoring data on the effluent of manufacturing facilities using triclosan pesticides. The first set of these data were received in April 2012 and will be the starting point for the EPA to assess any additional data needs and to conduct a quantitative environmental risk assessment during registration review.

Given the rapidly developing scientific database for this chemical, the agency accelerated the schedule for triclosan's re-evaluation (i.e., registration review) and issued a Final Work Plan for triclosan in April of 2014. This review of triclosan will entail new and comprehensive human health and ecological risk assessments, including endangered species assessments, for all the EPA-registered uses of triclosan. The EPA will take into consideration relevant information developed since the RED was issued, including information presented in the petition, comments submitted in response to the petition, peer reviewed literature, data received in response to the post-RED DCI, and incident reports, as well as any information obtained during the course of the registration review. This information will also include results of the ongoing studies being conducted by the National Toxicology Program (NTP) on triclosan as a result of the nomination of the chemical to NTP by the FDA, when such results are available. The EPA will review scientific literature studies in accordance with the published Office of Pesticide Programs (OPP) document Guidance for Identifying, Selecting, and Evaluating Open Literature Studies.[3] A Preliminary Risk Assessment is currently scheduled to be completed in late 2018. Documents associated with the registration review are available at regulations.gov in docket EPA-HQ-OPP-2012-0811.

III. Petition Response

A. *Response to Requests for Relief under FIFRA and FFDCA*

For the reasons set forth in more detail below, the EPA denies the request that the EPA suspend and cancel all registered products containing triclosan. The agency's most recent risk assessments of the risks to human health and the environment found that the antimicrobial uses of triclosan met the applicable statutory standards, and the petition and supporting comments did not provide sufficient evidence to significantly change those conclusions. In any event, the petition did not show that risks of concern from antimicrobial pesticidal uses of triclosan meet the criteria for suspending and canceling all registered products containing triclosan. Nonetheless, the agency is currently engaged in assessing the risks posed by triclosan through the risk assessment process in the registration review program. In general, the petition did not demonstrate that use of registered pesticides containing triclosan is causing

[3] http://www.epa.gov/pesticides/science/literature-studies.html

the harm alleged in the petition, or that the requested regulatory action would eliminate the harm alleged. EPA's responses to the various requests set forth in the petition are more specifically detailed below.

1. The petitioners believe that the widespread environmental and human exposure to triclosan has the potential to pose unreasonable risks to human health and the environment, particularly risks of endocrine disruption effects, and they request that the EPA reopen the RED for triclosan. The petition notes that the EPA has not completed the Endocrine Disruptor Screening Program (EDSP) required in the Food Quality Protection Act (FQPA) amendments to the FFDCA, and asserts that the RED "did not have the benefit" of whatever new knowledge or analysis might come out of that program (Pet. p. 22).

EPA Response: FIFRA requires the EPA to periodically review the registrations of all pesticides. The triclosan RED represents the agency's regulatory determination as of the time it was issued. In the RED, the agency committed to examining the endocrine interactions of triclosan further. The registration review process will provide the opportunity for the EPA to examine information developed since the RED and to require submission of additional data if necessary. The EDSP will provide an additional opportunity to assess the need to issue future orders or data call-ins requiring the submission of EDSP screening assays for triclosan.

2. The petition asserts that triclosan has the potential to promote bacterial resistance in humans to antibiotic medications and antibacterial cleansers, which is especially of concern for vulnerable subpopulations such as "persons with impaired immune systems, infants and young children, and persons needing the benefit of antibiotics" (Pet. p. 6). The petition also attributes bacterial resistance to "the widespread use of triclosan – whatever the source and whatever agency has regulatory authority," especially residues of triclosan left on surfaces from use of consumer products which are not regulated by the EPA (Pet. 27).

EPA Response: While scientists are understandably concerned about the potential for development of medication-resistant infectious bacteria, there is currently no direct evidence before the EPA, either from the petition or other sources, of a causal relationship between bacterial resistance in humans and either triclosan "body burden" or residential exposures to triclosan residues resulting from the use of consumer products. The agency has reviewed the information submitted in the petition and determined it does not demonstrate that bacterial resistance in humans results from pesticidal uses of triclosan, or that cancelling the registrations of triclosan-containing pesticide products would have any impact on the development of bacterial resistance since the pesticidal uses of triclosan constitute a very small percent of the triclosan used in the United States. In registration review, the agency will take into consideration relevant information developed since the RED was issued, including scientific literature studies in accordance with the published OPP document Guidance for Identifying, Selecting, and Evaluating Open Literature Studies.[4]

3. Based on the lipophilic nature of the compound, the petitioners assert that triclosan has the potential to bioaccumulate and pose an "immense body burden" to humans, resulting in the disruption of thyroid and other organ functions. They state that triclosan has been measured in quantifiable amounts in 75 percent of the U.S. population in urine, blood and breast milk.

EPA Response: The presence of triclosan in urine, blood, breast milk, and other bodily fluids does not by itself support a characterization of triclosan as bioaccumulative or posing an immense body burden.

[4] http://www.epa.gov/pesticides/science/literature-studies.html

The CDC survey that the petitioners cite found triclosan was present in the urine of 75 percent of a randomly surveyed population. The survey did not provide any evidence that the measured urine concentrations correlate with any adverse effects. Dayan (2007)[5] measured concentrations of triclosan in breast milk and concluded that exposures were well below the level of concern identified in the study for adverse effects of triclosan from breast milk ingestion. Further, as noted, biomonitoring studies such as the CDC and NHANES monitoring data account for all exposures of the individual to triclosan from every source, including those products and applications that are not pesticide products. Based on available data at the time of the 2008 RED, the agency concluded that total exposure to triclosan from all sources did not present risks of concern for human health. Additionally, since the pesticidal uses of triclosan constitute a very small percent of the triclosan used in the United States, there is no evidence that cancelling the triclosan pesticide registrations would meaningfully reduce the perceived body burden.

4. The petitioners also assert that secondary exposure to triclosan can result from triclosan not being completely removed from waste water and sludge, resulting in food and drinking water contamination.

EPA Response: While the petitioners identified waste water and sludge as potential sources of triclosan exposure, the agency would need data or other evidence of actual triclosan residues in any food or source of drinking water before it could assess the potential for such exposure to cause adverse effects. Also, since the NHANES biomonitoring data that the EPA used for the human health risk assessment accounted for exposure to triclosan from all possible sources, if secondary triclosan residues have been present in food or drinking water, that contribution to human exposure has been considered already and found to satisfy the risk-benefit regulatory standard under FIFRA. Finally, without any evidence that triclosan is present in waste water and sludge due to use of pesticides, EPA is unable to determine that any action it might take under FIFRA would actually reduce or mitigate that potential contribution to human exposure to triclosan. If the EPA finds evidence demonstrating exposure to pesticidal uses of triclosan causes unreasonable adverse effects in the environment during registration review, the agency will consider the appropriate regulatory action to take at that time.

5. In addition to exposure to triclosan, the petition maintains that the EPA has thus far failed to address major degradates of concern, including dioxins. The petition states that dioxins can be formed as impurities during the manufacture of many products containing triclosan, upon incineration of textile products treated with triclosan, in sunlight and in reaction with free chlorine in tap water.

EPA Response: While the agency did not consider dioxin contaminants as part of the RED, the EPA identified major degradates of concern in the Final Work Plan and has also examined the question of dioxin formation during the registration review of triclosan. A preliminary examination shows that the dioxins that can form from triclosan in chlorinated waters (2,7-dibenzodichloro-*p*-dioxin; 2,8-dichloro-*p*-dioxin; 1,2,8- and 2,3,7-trichlorodioxins and 1,2,3,8-tetrachlorodioxin) are not among the congeners that have been identified as being of toxicological concern (see the Triclosan Final Work Plan Appendices B and F for this discussion). Thus, EPA does not expect there to be risks of concern associated with dioxins formed with triclosan. This information is available in the docket for the Triclosan Registration Review at regulations.gov, docket EPA-HQ-OPP-2012-0811. The risk assessment that will be performed as part of registration review will include a discussion of dioxin formation from environmental concentrations of triclosan pesticide products.

[5] Dayan, A.D. 2007. Risk assessment of triclosan [Irgasan] in human breast milk. Food and Chemical Toxicology 45:125–129.

6. In addition to impacts on human health, the petition asserts that there is a potential for adverse ecological impacts from the continued registration of triclosan including bioaccumulation and the potential disruption of the ecosystem due to triclosan's toxicity to algae, "the first-step producers in aquatic ecosystems."

EPA Response: In the RED for triclosan, the EPA relied on a qualitative assessment of the potential for ecological effects to result from use of triclosan pesticide products, and found that no unreasonable adverse effects would occur. The EPA intends to further look into potential ecological effects and issued a data call-in (DCI) after issuance of the RED for several studies on the ecological effects and exposure potential of triclosan pesticides. Additionally, it is anticipated that ecological effects data will be required in registration review so that the agency can conduct a comprehensive ecological risk assessment at that time, including the potential for triclosan to bioaccumulate in environmental organisms.

7. The petitioners assert that "triclosan is 'misbranded' in violation of the FFDCA because it fails to provide the benefits claimed on product labels, in marketing and advertising campaigns and in other public statements in a cost-effective, safe manner."

EPA Response: The only type of product identified in this section of the petition was hand soap containing triclosan, a product that is regulated by the FDA, not the EPA, under the FFDCA.[6] Since these products do not fall within the EPA's jurisdiction under FIFRA, the EPA has no authority to grant any relief in response to this assertion.

B. *Response to Requests for Relief under Clean Water Act (CWA)*

The petitioners claim that with the continued registration of triclosan, the EPA has not restored and maintained the chemical, physical, and biological integrity of the Nation's waters. They claim that the EPA's failure to implement properly one federal environmental statute (FIFRA) directly enables a violation of another federal environmental statute (CWA). In the petitioners' opinion, they view the actions as "arbitrary, capricious" and "otherwise not in accordance with law." The petitioners request relief in three categories under the CWA. The petitioners request that the EPA impose technology-based effluent limitations guidelines (ELG), health-based toxic pollutant water quality pretreatment requirements, and biosolids regulation for triclosan. For the reasons set forth in more detail below, the EPA is denying the petitioners' requests to impose technology-based effluent limitations guidelines (ELG), health-based toxic pollutant water quality pretreatment requirements, and biosolids regulation for triclosan.

1. The petitioners request that the EPA impose technology-based effluent limitations guidelines (ELG) for triclosan. Petitioners allege that under the CWA, the EPA implements pollution control programs such as those setting wastewater standards for industry and water quality standards for all contaminants in surface waters. 33 U.S.C. §§1251, 1342, 1362(14) establishes "effluent limitations," in the form of nationally uniform, technology-based standards, and those standards ultimately apply to polluting "point sources."

EPA Response: There are currently effluent limitation guidelines (ELG) for several of the industries that involve products containing triclosan. There are effluent limitations guidelines for Soap and Detergent

[6] EPA does regulate pesticide residues in or on food by tolerance regulations under the FFDCA section 408, but that provision is not relevant to the products mentioned in the petition.

Manufacturing (1974), Textile Mills (1982), Organic Chemicals, Plastics, and Synthetic Fibers (1987), and Plastic Molding and Forming (1984). These are guidelines that cover water quality parameters such pH, Biological Oxygen Demand (BOD) and other parameters.

The EPA biennially publishes a plan, after public notice and comment that establishes a schedule for the annual review and revision of existing effluent guidelines and identifies any new industrial categories selected for effluent guidelines rulemaking and provides a schedule for such rulemaking. The EPA uses four major factors in prioritizing existing effluent guidelines or pretreatment standards for possible revision. The first factor the EPA considers is the amount and type of pollutants in an industrial category's discharge and the relative hazard posed by that discharge. The second factor the EPA considers is the performance and cost of applicable and demonstrated wastewater treatment technologies, process changes, or pollution prevention alternatives that could effectively reduce the concentrations of pollutants in the industrial category's wastewater and, consequently, reduce the hazard to human health or the environment associated with these pollutant discharges. The third factor the EPA considers is the economic achievability of the wastewater treatment technology, process change, or pollution prevention measures identified using the second factor. If the financial condition of the industry indicates that it would be difficult to implement new, more stringent requirements, the EPA might conclude that other approaches to a national rule might be appropriate. The fourth factor the EPA considers is an opportunity to eliminate inefficiencies or impediments to pollution prevention or technological innovation, or opportunities to promote innovative approaches, including within-plant trading.

The EPA's most recent evaluation of all industry categories concluded that discharges from the currently regulated industries involving products containing triclosan (including Soap and Detergent Manufacturing; Textile Mills; Organic Chemicals, Plastics, and Synthetic Fibers; and Plastic Molding and Forming) were not a hazard priority. For more information about the EPA's most recent evaluation, see 2012 Effluent Guidelines Program Plan, available at: http://water.epa.gov/scitech/wastetech/guide/304m/upload/Preliminary-2012-Effluent-Guidelines-Program-Plan.pdf.

2. The petitioners request that the EPA establish health-based toxic pollutant water quality pretreatment requirements for triclosan.

EPA Response: Industrial dischargers (manufacturers and formulators) may choose not to discharge directly into navigable waters and instead discharge indirectly through a publicly owned treatment works (POTW). CWA Section 307(b) (33 U.S.C. §1317(b)(1)) establishes pretreatment standards for pollutants that may be introduced into a POTW that are determined not to be susceptible to treatment by such treatment works or which would interfere with the operation of such treatment works. Pretreatment standards are established to prevent the discharge of any pollutant through a POTW where such pollutant interferes with, passes through, or otherwise is incompatible with such works. Indirect dischargers are subject to the pretreatment requirements of Section 307(b) of the CWA. The EPA annually investigates indirect industrial dischargers for the potential need for new or revised pretreatment standards concurrently with the ELG evaluation. To inform the most recent (2012) annual review, the EPA evaluated triclosan data taken from the 2009 Targeted National Sewage Sludge Survey (TNSSS)[7], discussed further below, to determine whether industrial categories can be identified as sources of chemicals that were measured in biosolids and, if so, whether new or revised pretreatment standards would be necessary. The EPA's evaluation did not find associations between triclosan in

[7] TNSSS: http://water.epa.gov/scitech/wastetech/biosolids/

sewage sludge and industrial wastewater discharges. Past EPA studies were consistent with this conclusion, having found that triclosan is present at highest concentrations in domestic wastewater, not industrial discharges. Thus, in the annual review the EPA determined that a water quality pretreatment standard was not appropriate at that time. As EPA has no different information since that determination, the EPA is, therefore, denying petitioners' request to establish a water quality pretreatment standard.

3. The petitioners request that the EPA impose biosolids regulation for triclosan, after a thorough evaluation of its health and environmental effects.

EPA Response: The CWA provides for the regulation of biosolids under CWA Section 405. Under Section 405, the EPA has promulgated the Biosolids Rule (40 C.F.R. part 503), a comprehensive rule for biosolids management, which is based on extensive risk assessments for select chemicals. Pursuant to the CWA, the EPA reviews the Part 503 standards not less than every two years for purposes of evaluating and regulating new pollutants, as needed.

In 2009 the EPA published the results of the Targeted National Sewage Sludge Survey (TNSSS)[6] which was designed to gather concentration data on 145 analytes that might occur in sewage sludge. The collected information was intended to help the EPA assess if exposures to analytes were occurring and whether the concentrations in sewage sludge may be of concern for public health and the environment. Triclosan was included in the TNSSS and found at concentrations ranging from 0.43 to 133 mg/kg. The EPA is evaluating TNSSS pollutants in two phases: 1) Phase I consists of evaluating ten pollutants (i.e., barium, beryllium, manganese, molybdenum, silver, 4-Chloroaniline, fluoranthene, pyrene, nitrate, and nitrite); the risk evaluations for these ten pollutants underwent peer review in early 2015, and the agency is addressing peer review comments. Following peer review, the agency will address comments, revise the risk evaluation technical background document, and consider any needed risk management options. 2) Phase II pollutants include 135 compounds (including triclosan) that the agency may evaluate starting in 2015 once the peer review is completed for the ten Phase I pollutants. The peer review for the Phase I pollutants may help inform the methodology for evaluating risk to humans and ecological (both terrestrial and aquatic) receptors, where sufficient data are available, and help determine if it is appropriate to impose biosolids regulations for the Phase II pollutants. The EPA is denying the petitioners' request to establish biosolids regulation for triclosan, however, because action is premature while these processes are pending.

C. *Response to Request for Relief under the Safe Drinking Water Act (SDWA)*

The petitioners claim that with the continued registration of triclosan, the EPA has violated the SDWA, in that triclosan would be allowed to contaminate drinking water at levels that threaten human health and the environment. The petitioners request that the EPA conduct a comprehensive assessment of the appropriateness of regulating triclosan under the SDWA.

EPA Response: As discussed in more detail below, the EPA already assesses triclosan for regulation under the SDWA, so there is no need for any further action under this petition. The EPA is neither granting nor denying the petition with respect to the requested SDWA assessment.

The CCL[8] is a list of contaminants that are currently not subject to any proposed or promulgated national primary drinking water regulations, that are known or anticipated to occur in public water systems, and which may require regulation under the SDWA. EPA uses the CCL to identify priority

[8] Drinking Water Contaminant Candidate List (CCL) and Regulatory Determination: http://www2.epa.gov/ccl

contaminants for regulatory decision making under SDWA and for research and data collection. The CCL 3[9] was published in October 2009 and includes, among others, pesticides, disinfection byproducts, chemicals used in commerce, waterborne pathogens, pharmaceuticals, and biological toxins. The agency considered the best available data and information on health effects and occurrence to evaluate the contaminants on the list. EPA used a multi-step process that was recommended by the National Academies of Science's National Research Council and the National Drinking Water Advisory Council in order to determine which chemicals, chemical groups, or microbiological contaminants should be included on the Final CCL 3. The first step in the CCL 3 process included identifying a broad universe of almost 7,500 potential microbial and chemical drinking water contaminants (called the CCL 3 Universe). EPA then applied screening criteria to the CCL 3 Universe based on a contaminant's potential to occur in public water systems and the potential for public health concern to identify a Preliminary CCL (PCCL) of about 600 contaminants. EPA then evaluated the contaminants on the PCCL based on a more detailed assessment of occurrence and health effects using a scoring and classification system and expert judgment to develop the Draft CCL 3. Public input and expert review were incorporated throughout the CCL 3 process, including an opportunity for public comment on the Draft CCL 3 and review of the draft list by EPA's Science Advisory Board. The Final CCL 3 includes 104 chemicals or chemical groups and 12 microbiological contaminants.

Triclosan was included in the universe of contaminants initially considered and evaluated for the CCL 3. After evaluating the best available health effects and occurrence data, triclosan did not pass screening to the Preliminary CCL (PCCL), and it was not included on the CCL 3 because the data indicated it did not typically occur in public water systems at levels of concern to human health. EPA sought public nominations for contaminants to be considered for possible inclusion in the fourth CCL (CCL 4)[10] in May 2012. Triclosan was nominated by the public. No new quantitative health effects data were identified by EPA or submitted by the public during the nominations period that could be used in screening or scoring triclosan for CCL 4. Additionally, no new occurrence data were identified by EPA or submitted by nominators that were not already considered under CCL 3. On February 4, 2015, EPA published the Draft CCL 4 with an opportunity for public comment, and will consider any relevant new occurrence and health effects data in finalizing the CCL 4. 80 FR 6076.

D. *Response to Request for Relief under the Endangered Species Act*

The petitioners request that the EPA "comply fully" with the ESA by conducting a biological assessment and engaging in consultation with the Secretary of the Interior and the Secretary of Commerce.

EPA Response: As part of the registration review process, the agency has committed to meet its obligations under the Endangered Species Act to determine whether or not a pesticide's use has an effect on a threatened or endangered species. As discussed above, the agency will perform a comprehensive ecological risk assessment that will allow the agency to determine whether triclosan's use as an antimicrobial pesticide has "no effect" on or "may affect" federally listed threatened or endangered species ("listed species") or their designated critical habitats. That assessment will determine whether the agency will consult with the U.S. Fish and Wildlife Service or the National Marine Fisheries Services (the Services), as appropriate. Therefore, the EPA grants the petition's request for relief under the ESA.

[9] Contaminant Candidate List 3: http://www2.epa.gov/ccl/contaminant-candidate-list-3-ccl-3

[10] Draft Contaminant Candidate List 4: http://www2.epa.gov/ccl/draft-contaminant-candidate-list-4-ccl-4

IV. Conclusion

For the reasons set forth above, the agency concludes that the petitioners have not carried their burden of demonstrating the appropriateness of the requested relief. The EPA has previously determined that pesticide products containing triclosan will not cause unreasonable adverse effects on human health or the environment. As part of the EPA's statutory obligation to periodically review all registered pesticides, the EPA has initiated another comprehensive assessment of the risks and benefits of triclosan pesticide products through the registration review process. The EPA will take the information provided by the petition and the commenters into account when conducting the registration review risk assessments. The EPA will use that process to determine whether or not regulatory action such as cancellation is warranted. Therefore, the EPA denies the request to cancel triclosan registrations. Suspension of a pesticide's registration is an interim remedy under FIFRA that must be accompanied by the initiation of a cancellation action; because the EPA has determined that it will not initiate cancellation at this time, the request that the EPA suspend the registrations of triclosan products is also denied. The EPA grants the petition's request for relief under the ESA, in as much as the agency will assess risks to listed species in the triclosan registration review.

The EPA is also denying the petition's request to establish new regulations for triclosan under the CWA at this time. The agency is engaged in ongoing assessments and analyses to consider whether new limitations on chemicals, including triclosan, are necessary, including evaluating the results of the TNSSS. If such evaluations lead the EPA to conclude in the future that new controls are necessary, the agency will consider taking appropriate actions.

The EPA is neither granting nor denying petitioners' requests to conduct assessments under the SDWA, as the agency is already pursuing these actions.

If you have any questions concerning this response, please contact Sandra O'Neill at (703) 347-0141.

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