

**CITIZEN PETITION TO THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY**

_____)
FOOD & WATER WATCH,)
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BEYOND PESTICIDES)
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 Petitioners,)
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Filed With:)
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UNITED STATES ENVIRONMENTAL)
PROTECTION AGENCY and)
Lisa Jackson, Administrator)
)
)
_____)

Docket No.

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CITIZEN PETITION FOR A BAN ON TRICLOSAN

Introduction

Petitioners Beyond Pesticides and Food & Water Watch, acting through counsel, hereby submit this Citizen Petition for a Ban on Triclosan (Petition). Petitioners are non-profit organizations engaged in research, education and advocacy on behalf of the public, seeking to protect public health and safety and the environment from the adverse effects of widespread triclosan usage.

Petitioners' Right to Petition

This Petition is submitted pursuant to the right to petition government contained in the First Amendment of the United States Constitution,¹ the Administrative Procedure Act² (APA), the Federal Insecticide, Fungicide, and Rodenticide Act³ (FIFRA), the Federal Food Drug and Cosmetic Act (FFDCA),⁴ the Federal Water Pollution Control Act⁵ (Clean Water Act or CWA), the Safe Drinking Water Act⁶ (SDWA) and the

¹ U.S. Const., Amend. I. (“Congress shall make no law ... abridging ... the right of the people ... to petition Government for a redress of grievances.”). The right to petition for redress of grievances is among the most precious of the liberties safeguarded by the Bill of Rights. *United Mine Workers of Am., Dist. 12 v. Illinois State Bar Ass’n*, 389 U.S. 217, 222 (1967). It shares the “preferred place” accorded in our system of government to the First Amendment freedoms, and has a sanctity and a sanction not permitting dubious intrusions.” *Thomas v. Collins*, 323 U.S. 516, 530 (1945). “Any attempt to restrict those First Amendment liberties must be justified by clear public interest, threatened not doubtful or remotely, but by clear and present danger.” *Id.* The Supreme Court has recognized that the right to petition is logically implicit in, and fundamental to, the very idea of a republican form of government. *United States v. Cruikshank*, 92 U.S. (2 Otto) 542, 552 (1875).

² 5 U.S.C. § 553(e) (2005) (“Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.”).

³ 7 U.S.C. § 136w et seq.

⁴ 21 U.S.C. §§ 301 et seq.

⁵ 33 U.S.C. §1251 et seq.

⁶ 42 U.S.C. § 300f-300j-26.

Endangered Species Act⁷ (ESA). Petitioners request that the Administrator of the Environmental Protection Agency (EPA) use her authority under FIFRA, the FFDCA, the CWA, the SWDA and the ESA to grant any and all remedies available under relevant federal law.

Triclosan; Characteristics, Uses and Regulatory Agencies

Triclosan is a synthetic, broad-spectrum antimicrobial chemical that is currently used extensively in a wide range of consumer products. These products fall under the jurisdiction of both the United States Food and Drug Administration (FDA) and the EPA. For those products under EPA's jurisdiction, EPA decided in 2008 that the currently registered uses of triclosan are eligible for "reregistration."⁸ This Petition is submitted based primarily on the steadily increasing scientific knowledge and consensus about triclosan's adverse effects on public health and safety and the environment. Petitioners also address the EPA RED's analysis in order to illustrate the inadequacies of past EPA analyses and conclusions about triclosan.

Summary of Relief Sought and Scientific Grounds

1. Specific Relief Requested

Petitioners urge the Administrator to grant the following relief in this Petition:

FIFRA and FFDCA

- Reopening the RED;
- Suspension and Cancellation (Petitioners' principal requested relief) ; and
- Any Other Remedies Called for by Federal Law.

⁷ 7 U.S.C. §136; 16 U.S.C. §460 et seq.

⁸ Environmental Protection Agency, Final Reregistration Eligibility Decision for triclosan (RED).

CWA

- Technology-Based Effluent Limitations;
- Health-Based Toxic Pollutant Water Quality Pretreatment Requirements;
- Biosolids Regulation.

SDWA

- Comprehensive assessment of appropriateness of listing and regulation.

ESA

- Consultation with the Secretary of the Interior and the Secretary of Commerce;
- Preparation of a Biological Assessment.

2. *The Remedy Should Be Based on “Transparency and Sound Science.”*

Petitioners believe that applicable law and science justify the relief requested below and that therefore the Administrator should act decisively. In this regard, Petitioners endorse the approach and the policies applied by the Administrator in EPA’s decision to launch “a comprehensive new evaluation of the pesticide atrazine to determine its effects on humans.”⁹ In the case of triclosan, however, Petitioners will demonstrate that the scientific evidence and the legal authorities are so substantial as to require suspension of the registered uses of triclosan pending agency deliberations regarding cancellation.

In making its “new evaluation” of atrazine, EPA will investigate its potential effects with respect to cancer and non-cancer effects on humans, birth defects,

⁹ See EPA. *EPA Begins New Scientific Evaluation of Atrazine*. 10/07/2009.
<http://yosemite.epa.gov/opa/admpress.nsf/d0cf6618525a9efb85257359003fb69d/554b6abea9d0672f85257648004a88c1!OpenDocument>

low birth weight, premature births and amphibians and aquatic ecosystems.¹⁰ Steve Owens, Assistant Administrator for EPA's Office of Prevention, Pesticides and Toxic Substances, explained EPA's decision to reconsider its past approvals of atrazine as follows:

One of Administrator Jackson's top priorities is to improve the way EPA manages and assesses the risk of chemicals, including pesticides, and as part of that effort, we are taking a hard look at the decision made by the previous administration on atrazine ... Our examination of atrazine will be based on transparency and sound science, including independent scientific peer review, and will help determine whether a change in EPA's regulatory position on this pesticide is appropriate."¹¹

Petitioners believe that the same scientific and legal grounds exist in regard to the potential adverse health and environmental effects of triclosan as do in regard to atrazine, and, given the widespread public and environmental exposure to it, a mandate exists for urgent action to suspend the uses stipulated in this Petition. Accordingly, Petitioners assert that the relief requested below is soundly based and is justified.

3. *Summary of Major Scientific Points*

The major points presented in this Petition are the following:

- **Endocrine Disruption.** Endocrine disruption is another potential result of triclosan bioaccumulation in the body. This effect, in turn, poses serious

¹⁰ *Id.*

¹¹ *Id.*

threats to thyroid and other organ functions, and it can also influence the development of cancer.

- **Bacterial Resistance.** Bacterial resistance to antibiotic medications and antibacterial cleansers is just one category of threats emanating from the growing body burden of triclosan. Such resistance renders humans (especially vulnerable subpopulations) wide open to bacteria-induced illnesses and death;
- **Body Burden.** The presence of triclosan in the human body (as evidenced by scientific studies of its activity in blood, urine and breast milk) imposes an immense and dangerous “body burden.” This presence raises concerns about a multitude of threats to humans;
- **Wastewater, Sludge and Food Contamination.** Wastewater contamination by triclosan is a serious health threat. Importantly, triclosan products used in the home and in the workplace typically yield residues that flow into wastewater from rinsing, cleaning and other normal activities. Because these residues are not rendered harmless by the wastewater treatment process, they are free to reenter the environment—and ultimately the human body;
- **Failure to Address Major Degradates.** Once in the larger environment, triclosan poses numerous additional dangers:

- It may be transformed into dioxin and chloroform when exposed to sunlight under certain conditions, thus creating the threat of cancer development;
- **Aquatic and Other Ecosystem Impacts.** Because it is present in the larger environment, triclosan can be highly toxic to different types of algae, thus creating both specific threats as well as potential destruction of larger ecosystem balance. Threatened and endangered species and their habitat, to the extent they come into contact with sufficient quantities of triclosan, are vulnerable.
- **Efficacy.** Numerous scientific studies and reports indicate that triclosan is not any more effective than many safer, less-expensive products. Therefore, consumers and other users of triclosan products suffer, at a minimum, economic detriment from having purchased a product that is unnecessarily costly, and, in the worst case, poses potential danger to their health and safety.
- **Organizational Actions and Decisions Targeting Triclosan.** As a result of the rapidly mounting evidence, serious concerns about triclosan's safety and efficacy have led a number of governmental, professional, corporate and other organizations to condemn or reject that substance as appropriate for many uses in society.

These points are discussed in detail in Section II of this Petition.

I. Environmental Laws Violated by Triclosan Usage, and the Administrator's Authority to Take Action to Protect Public Health and Safety and the Environment and the Requested Relief

The Federal Insecticide, Fungicide and Rodenticide Act,¹² (FIFRA) and the Federal Food, Drug and Cosmetic Act¹³ (FFDCA) are the principal statutes relied upon in this Petition. Nonetheless, the pervasive and widespread use of triclosan, along with its particular characteristics and the nature of its authorized uses, has also triggered actual or potential violations of certain other federal statutes. This section describes the various statutes invoked by this usage.

A. Federal Insecticide, Fungicide and Rodenticide Act and the Federal Food, Drug and Cosmetic Act

1. Objectives, Structure and Relevant Legal Provisions

Under FIFRA, EPA may not register a “pesticide” unless the chemical will perform its intended function without causing any “unreasonable adverse effects on the environment.”¹⁴ This effect is defined as “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.”¹⁵

Regulatory Jurisdiction of EPA and FDA

EPA and the FDA both have major regulatory mandates regarding substances like triclosan.¹⁶ Further, the two agencies have concurrent jurisdiction over certain substances

¹² 7 U.S.C. § 136w et seq.

¹³ 21 U.S.C. §§ 301 et seq.

¹⁴ 7 U.S.C. § 136a(c)(5)(C).

¹⁵ 7 U.S.C. §136(bb).

¹⁶ *Memorandum of Understanding Between the Environmental Protection Agency and the Food and Drug Administration, Drug/Pesticide Products for Use on or in Animals*, 48 Fed. Reg. 22799 (May 20, 1983); *Enforcement of the Federal Insecticide, Fungicide and Rodenticide Act, Registration, Reregistration and*

and uses. Examples include: sanitizers for food contact surfaces; microbiocides in packaging coming into contact with food; antimicrobial agents used on medical devices; and substances used to control microorganisms in cane sugar and beet sugar mills.¹⁷

EPA Regulation

Although EPA's regulatory mandate under FIFRA covers a number of activities, the most pertinent ones to this Petition are registration (including reregistration), labeling and pesticide residue tolerances.

FIFRA Section 3(a) prohibits the distribution or sale of a pesticide that is not registered under that statute.¹⁸ The Administrator will register a pesticide upon a determination, subject to any applicable restrictions, that: its composition is such as to warrant the proposed claims about it; its labeling and other submitted material comply with FIFRA; it will perform its intended function without unreasonable adverse effects on the environment; and when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.¹⁹

The reregistration review requirements imposed on EPA by FIFRA reflect an increasing concern for protection of human health and the environment. Indeed, a series of statutory amendments to FIFRA, including the Federal Insecticide, Fungicide and Rodenticide Act Amendments of 1988, the Food Quality Protection Act of 1996 and the

Classification Procedures, 44 Fed. Reg. 63749 (Nov. 5, 1979) (Update to Memorandum of Agreement); *Agreement Between Department of Health, Education and Welfare and Environmental Protection Agency, Notice Regarding Matters of Mutual Responsibility, Amendment*, 38 Fed. Reg. 24233 (Sept. 6, 1973)(regulatory exemption from FIFRA of certain products subject to the FFDCA); *Agreement Between Department of Health, Education and Welfare and Environmental Protection Agency, Notice Regarding Matters of Mutual Responsibility*, 36 Fed. Reg. 24234 (Dec. 22, 1971).(Memorandum of Agreement).

¹⁷ E Brown, A Claassen, C Hathaway, J Homstead, T Powell, W Wehrum, K Weinstein, *Pesticide Regulation Deskbook*, 12 (2000).

¹⁸ 7 U.S.C. § 136a(a).

¹⁹ 7 U.S.C. § 136a(c)(5)(A)-(D).

Pesticide Registration Improvement Act of 2003, all evidence a growing consensus in society and among public policymakers that strict regulation of pesticides is vital to the health and safety of humans and the ecosystems of which they are a part.²⁰

Each Phase of the reregistration review process reflects this emphasis. In particular, currency and completeness of pertinent data and studies, as well as thorough and comprehensive assessment by the agency, lie at the heart of the process. Section 4 (a) of FIFRA requires the EPA Administrator to reregister each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984.²¹ Triclosan was first registered by EPA in 1969. Having completed Phase V of its reregistration review for triclosan, has issued the present final RED.

FIFRA contains several statutory provisions authorizing the Administrator to ban or otherwise restrict the manufacture, labeling and sale of a pesticide when use of that pesticide would have unreasonable adverse effects on humans and the environment. These provisions include: registration and re-registration; suspension and cancellation of pesticide registrations; special review; notice of warning; civil penalties; civil administrative proceedings; supplemental environmental projects; stop sale, use, or removal orders; seizure; injunction; and criminal proceedings.

The Federal Food, Drug and Cosmetic Act²² (FFDCA) was first enacted by Congress in 1938 to provide a comprehensive mandate for the federal Food and Drug

20 See, FIFRA Amendments of 1988, Press Release, October 26, 1988, available at <http://www.epa.gov/history/topics/fifra/01.htm>. "I am pleased with this bill and want to commend Congress for this action," said EPA Administrator Lee M. Thomas. "It will go a long way toward assuring safer pesticide use."

21 7 U.S.C. § 136a-1(a).

22 21 U.S.C. §§ 301 et seq.

Administration (FDA) in its oversight of food, drug, and cosmetic safety.²³ FFDC Section 408 authorizes EPA to set tolerances, or maximum residue limits, for pesticide residues on foods. The FFDC was amended in 1996 by the Food Quality Protection Act to impose enhanced standards for the protection of not only adults, but also children, infants and other vulnerable subpopulations. In setting tolerances, EPA must make a finding that the tolerance is “safe.” Safe is defined as meaning that there is a “reasonable certainty that no harm will result from aggregate exposure to the pesticide residue.”²⁴

EPA possesses certain authority to protect the public from unsafe pesticide residues. This authority includes: establishment of a tolerance or grant of a tolerance exemption; modification, suspension or revocation of the tolerance; requirement of submission of additional data or information.

2. Violations of Law and Requested Relief

In their December 2008 Comments on EPA/OPP Reregistration Eligibility Decision for Triclosan (EPA Comments)²⁵, Petitioners described the FIFRA violations being allowed by EPA’s reregistration of triclosan:

EPA ... continues to ignore serious risks posed to public health. The agency has 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. As such, the agency has

²³ 21 U.S.C. §301 et seq.

²⁴ 21 U.S.C. § 346a (a)-(c).

²⁵ Comment on Proposed Rule, Triclosan: Reregistration Eligibility Decision, Notice of Availability. Document ID: EPA-HQ-OPP-2007-0513-0053. (EPA Comments), Available at www.regulation.gov. See Appendix B for complete list of signatories.

still not proven that triclosan poses “no unreasonable adverse effects” to human health and the environment.²⁶

Petitioners take the position that the EPA RED, depending on the specific topic addressed, contains incomplete data, inadequate analysis, or both. Such a failure, in Petitioners’ view is “arbitrary, capricious” and “otherwise not in accordance with law.”²⁷ Even EPA itself acknowledged the substantial uncertainty lying at the core of its own decision. Noting the “considerable amount of ongoing research regarding triclosan” and the “rapidly developing scientific database” for the chemical, EPA intends to “accelerate the schedule for the reregistration review process” by ten years.²⁸

Indeed, the research has been ongoing and the scientific database has developed considerably. It is, in fact, in light of not only the research studies and organizational responses identified and discussed in Petitioners’ EPA Comments but also in light of subsequent studies and responses to them that this Petition is being submitted. Because of the agency’s incomplete and inadequate assessments in its past decisions, Petitioners request that the Administrator now take decisive action.

Petitioners strongly believe that the suspension/cancellation remedy is the most appropriate remedy, in light of the magnitude of the health threat posed by triclosan. . 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 is present in most people’s bodies, EPA must take the most protective steps provided for

26 Id.

27 5 U.S.C. § 506(2)(a). See also, *Love v. Thomas*, 858 F.2d 1347 (9th Cir. 1988); *National Grain Sorghum Producers Assoc., Inc. v. EPA*, 84 F.3d 1452 (D.C. Cir. 1996).

28 EPA RED, p. 41.

under the statute to protect public health. Again, the suspension/cancellation remedy was expressly contemplated by Congress as remedy for such a potent threat. 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.

Further, Petitioners' preferred remedy of suspension/cancellation is particularly appropriate because EPA's decisions allowing, in effect, violations of FIFRA and the FFDCA also "enable" violations of other federal environmental statutes. (See the discussions below of the CWA, the SDWA and the ESA.) Petitioner's overall point in this regard is that EPA's mandate under FIFRA and the FFDCA *must* be viewed in the context of its overall mandate as an agency to protect public health and the environment. Indeed, this point has met with the approval of the federal courts, as reflected in the following sections below.

B. Clean Water Act

1. Objectives, Structure and Relevant Legal Provisions

The Federal Water Pollution Control Act²⁹ (Clean Water Act or CWA) is the primary statutory basis for regulating discharges of pollutants into the waters of the United States and for regulating water quality standards. The United States Supreme Court has observed that in the CWA, Congress intended to regulate water pollution to the full extent of the United States Constitution's Commerce Clause.³⁰ As set forth in Section 101(a), the CWA's objective is "to restore and maintain the chemical, physical, and

²⁹ 33 U.S.C. §1251 et seq.

³⁰ *United States v. Riverside Bayview Homes*, 474 U.S. 121 (1985).

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 pollutions in toxic amounts.”³¹

Technology-Based Regulation

Under the CWA, EPA has implemented pollution control programs such as those setting wastewater standards for industry and water quality standards for all contaminants in surface waters. Pertinent to this Petition, CWA Section 301 (a) makes “the discharge of any pollutant by any person ... unlawful” unless that discharge is in compliance with relevant CWA provisions.³² Accordingly, the statute requires the Administrator to establish “effluent limitations,” in the form of nationally uniform, technology-based standards, and those standards ultimately apply to polluting “point sources.”³³ The vehicle for imposing these standards upon individual point sources is the “National Pollutant Discharge Elimination System” (NPDES) permit, which allows the “discharge” of pollutants into navigable waters by point sources--subject to such “conditions” as will assure compliance with the statute’s objectives.³⁴

Health-Based Water Quality Regulation; Toxic Pollutants

In addition to the imposition of technology-based effluent limitations for point source discharges, the CWA also authorizes the establishment of water-quality-based standards.³⁵ These more stringent health-based standards recognize that technology-based

³¹ 33 U.S.C. §1251(a)(1),(2), (3).

³² 33 U.S.C. §1311(a).

³³ 33 U.S.C. §§1251, 1342, 1362(14).

³⁴ 33 U.S.C. §1342(a).

³⁵ 33 U.S.C. §§1312, 1313. *See, Natural Resources Defense Council v. Environmental Protection Agency*, 915 F.2d1314 (9th Cir. 1990).

effluent limitations alone may not achieve the desired levels of water quality in a given circumstance. Among these standards are those for regulation of “toxic pollutants” under Section 307.

CWA Section 307(a)(1) authorizes the Administrator to revise the list of regulated toxic pollutants originally identified in that statute by adding or removing a pollutant. In so doing, the Administrator “shall take into account toxicity of the pollutant, its persistence, degradability, the usual or potential presence of affected organisms in any waters, the importance of affected organisms, and the nature and extent of the effect of the toxic pollutant on such organisms.”³⁶ Effluent limitations issued taking Section 307 toxic pollutants into account “shall be set at that level which the Administrator determines provides an *ample margin of safety*.”³⁷ (Emphasis added)

Pretreatment of Toxic Pollutants

Industrial dischargers may choose not to discharge directly into navigable waters. Instead, they discharge “indirectly” into navigable waters through a POTW. Indirect dischargers, unlike direct dischargers, are not subject to a national permit program, but they are subject to the pretreatment requirements of CWA Section 307(b).³⁸

CWA Section 307(b) requires that the Administrator establish pretreatment standards for [toxic pollutants] that may be introduced into publicly owned treatment works (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 “shall be established to prevent the discharge of any pollutant through [POTW]

³⁶ 33 U.S.C. §1317(a)(1).

³⁷ 33 U.S.C. §1342(a)(4).

³⁸ See, 2 W. RODGERS, ENVIRONMENTAL LAW 463-64 (1986).

which pollutant interferes with, passes through, or otherwise is incompatible with such works.”³⁹

Regulation of Biosolids

The CWA also provides for the regulation of “biosolids,” which are the nutrient-rich organic solid, semisolid or liquid residue generated during the treatment of domestic sewage in a POTW.⁴⁰ Biosolids may be recycled and applied as fertilizer to soils, or it may be disposed of in other ways. CWA Section 405(a) provides:

[W]here the disposal of sewage sludge resulting from the operation of a treatment works ... would result in any pollutant from such sewage sludge entering the navigable waters, such disposal is prohibited except in accordance with a permit issued by the Administrator.⁴¹

Pursuant to CWA Section 405, EPA has developed regulations for the permitted disposal and utilization of biosolids, including the identification of toxic pollutants that:

on the basis of available information on their toxicity, persistence, concentration, mobility, or potential for exposure, may be present in sewage sludge in concentrations which may adversely affect public health or the environment.⁴²

As mandated by CWA Section 405, EPA has promulgated the “Biosolids Rule,”⁴³ a comprehensive rule for biosolids management that the agency asserts is based on

³⁹ 33 U.S.C. §1317(b)(1)..

⁴⁰ “Sewage sludge” is (the name for the solid, semisolid or liquid residue generated during the treatment of domestic sewage in a treatment facility)

⁴¹ 33 U.S.C. § 1345(a).

⁴² 33 U.S.C. § 1345(d)(2)(A)(i).

⁴³ 40 C.F.R. Part 503. See also, 58 Fed. Reg. 9248-9404, Feb. 19, 1993.

extensive risk assessment.⁴⁴ EPA's earlier attempts at establishing a biosolids management rule were rejected by the federal courts as inadequate on numerous occasions. Ultimately, these rejections, as well as Congressional action, in the form of the Water Quality Act of 1987, forced proper action by the agency.⁴⁵

The EPA Administrator's authority to set standards regulating pollutant discharges and water quality—and take action against violations-- is considerable. This authority includes: effluent limitations; **toxic** and pretreatment effluent standards (triclosan degradate 2,4 dichlorophenol is a noted CWA priority pollutant under Section 307(a); pretreatment is required under Section 307(b) to protect wastewater treatment plants); records and reports; inspections; enforcement (administrative, civil, or criminal penalties; injunctive relief; administrative orders; civil judicial action; compliance orders; civil penalties; criminal penalties); oil and hazardous substance liability; national pollutant discharge elimination system (NPDES); permits for dredged or fill material; disposal or use of sewage sludge (EPA Biosolids rule protects public health from certain pollutants and contaminants present in wastewater residues (40 CFR part 503); and emergency powers (imminent and substantial endangerment).

2. Violations of Law and Requested Relief

With the continued registration of triclosan, EPA has allowed the chemical and biological integrity of the nation's waterways. As noted in Section II(D) of this Petition, the USGS finds that triclosan is one of the most frequently detected compounds and at

⁴⁴ See US Environmental Protection Agency, Office of Wastewater Management, A Plain English Guide to the EPA Part 503 Biosolids Rule, EPA/832/R-93/003, at 1 (September 1994).

⁴⁵ See generally, *Natural Resources Defense Council v. EPA*, 790 F.2d 289 (3d Cir. 1986); *Chicago Ass'n of Commerce & Indus. v. EPA*, 873 F.2d 1025 (7th Cir. 1989); *Armco, Inc. v. EPA*, 869 F.2d 975 (6th Cir. 1989). See also, *Sierra Club v. EPA*, 992 F.2d 337 (D.C. Cir. 1993) (holding that EPA's 1991 revisions to the sludge management guidelines complied with CWA Section 405(d)); Water Quality Act of 1987, Public Law No. 100-4.

some of the highest concentrations in of the nation's waterways and levels of concern (LOCs) are already exceeded for aquatic plants according to EPA's own assessment. As Sections II(A) and (F) of this Petition observe, studies have found that triclosan accumulates in fish, shellfish and possibly other aquatic organisms which may result in endocrine disrupting activities in these organisms. Endocrine disruption impairs the reproductively of many aquatic species with devastating effects on species, including their population size and propagation.

Notably, 2,4-Dichlorophenol (2,4-DCP), which is a transformation product of triclosan, has been listed in accordance with Sec 307(a) and as a result, has established water quality standards for surface waters. According to scientific studies and EPA's 2008 assessment, described in Section II(E) of this Petition, triclosan in waterways transforms (93.8-96.6%) to 2,4-dichlorophenol, potentially leading or contributing to the violation of the set water quality standards set under the CWA. This is an example of how EPA's failure to implement properly one federal environmental statute (FIFRA) directly enables a violation of another federal environmental statute (CWA). Further, caselaw has firmly established that *even* in situations in which FIFRA has not been violated the CWA must be respected:

[W]here the herbicide will enter the waters of the United States, FIFRA provides no method for analyzing the local impact and regulating the discharge from a particular point source. *The NPDES permit requirement under the CWA thus provides the local monitoring that FIFRA does not.*⁴⁶ (Emphasis supplied)

⁴⁶ *Headwaters, Inc. v. Talent Irrigation Dist.*, 243 F.3d 526, 531 (9th Cir. 2001).

In conclusion, numerous studies, including those of EPA, have established the substantial presence, and therefore the 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."⁴⁷ 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 toxic pollutant water quality pretreatment requirements, and biosolids regulation.

Safe Drinking Water Act

1. Objectives, Structure and Relevant Legal Provisions

The Safe Drinking Water Act⁴⁸ (SDWA) authorizes the United States Environmental Protection Agency (US EPA) to set national health-based standards for drinking water to protect against both naturally-occurring and man-made contaminants that may be found in drinking water. US EPA, states, and water systems then work together to make sure that these standards are met. EPA sets a health goal based on risk (including risks to the most sensitive people, such as infants, children, pregnant women, the elderly, and the immuno-compromised). EPA then sets a legal limit for the contaminant in drinking water or a required treatment technique. This limit or treatment technique is set to be as close to the health goal as feasible.

The Administrator has numerous powers under the SDWA to regulate against the

⁴⁷ 5 U.S.C. § 506(2)(a).

⁴⁸ 42 U.S.C. § 300f-300j-26.

health and environmental threats sought to be avoided under that statute. These powers include: listing and regulation of a contaminant under National Primary Drinking Water Regulations; notice to state and public water system; issuance of administrative order; civil action; and enforcement in nonprimacy states.⁴⁹

2. Violations of Law and Requested Relief

In the same manner as is true with the CWA, EPA's reregistration decision sets the stage for a violation of SDWA, 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.

C. Endangered Species Act

1. Objectives, Structure and Relevant Legal Provisions

The Endangered Species Act⁵⁰ (ESA) provides a program for the conservation of threatened and endangered plants and animals (species) and their habitats. Under ESA, federal agencies are prohibited from authorizing, funding, or carrying out activities that are likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of their designated critical habitats. The law also prohibits any action that causes a "taking" of any listed species of endangered fish or wildlife.

The ESA confers certain mandates and authorities upon the Administrator, in aid of protection for threatened and endangered species and their habitats. These include:

⁴⁹ 42 U.S.C. § 300g-3(a)-(b).

⁵⁰ 7 U.S.C. §136; 16 U.S.C. §460 et seq.

consultation with the Secretary of the Interior or the Secretary of Commerce⁵¹ and preparation of a Biological Assessment.⁵²

2. Violations of Law and Requested Relief

Because triclosan is present in the larger 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.⁵³

II. Statement of Scientific Grounds

A. The Ubiquity of Triclosan Results in Endocrine Disruption

In its RED, EPA admits that it retained its current endpoints notwithstanding that it is aware of recent research conducted by its Office of Research and Development on the effects of triclosan on thyroid homeostasis in the rat. EPA determined, however, that "further investigation is needed on the effects of triclosan on the thyroid"⁵⁴ before inclusion of this endpoint. Thus, EPA declined to require full and rigorous assessment of this significant health threat even though it acknowledges that there exists "some evidence that triclosan disrupts thyroid hormone homeostasis and interacts with the

⁵¹ 16 U.S.C. § 1536(a).

⁵² 16 U.S.C. § 1536(c).

⁵³ See, *Defenders of Wildlife v. EPA*, 882 F.2d 1294 (8th Cir. 1989).

⁵⁴ EPA RED, p. 13.

androgen and estrogen receptors.”⁵⁵ As the discussion below demonstrates, there exists considerable evidence of these effects, and, further, that evidence continues to mount. Indeed, research conducted and recently published by EPA scientists demonstrates that triclosan interferes with circulating levels of thyroid and testosterone hormone levels in male juvenile rodents.⁵⁶ Further, EPA was recently advised by the National Research Council to consider the cumulative effects of chemicals with similar toxicological outcomes, including neurodevelopmental toxins.⁵⁷

Finally, in its failure to perform a proper assessment, EPA flouted a Congressional determination that endocrine disruption is a serious health threat that merits proper evaluation of substances that can potentially cause that phenomenon. That is, in the Food Quality Protection Act amendments to the Federal Food, Drug and Cosmetics Act (FFDCA), EPA was required to establish an Endocrine Disruptor Screening Program⁵⁸ (EDSP). Yet, establishment of the EDSP has not been completed, and thus the RED process did not have the benefit of its potential for promoting more complete and accurate assessment of this important threat to human health.

General Endocrine Disruption

Triclosan has been demonstrated to bioaccumulate and have endocrine effects in

⁵⁵ EPA RED, p. 35.

⁵⁶ Crofton, KM; Paul, KB; DeVito, MJ; Hedge, JM. *Short-term in vivo exposure to the water contaminant triclosan: Evidence for disruption of thyroxine*. Environ Toxicol Pharmacol. 2007. 24: 194–197, and Zorrilla LM, Gibson EK, Jeffay SC, Crofton KM, Setzer WR, Cooper RL, Stoker TE. *The effects of triclosan on puberty and thyroid hormones in male Wistar rats*. Toxicol Sci. 2009 Jan;107(1):56-64. Epub 2008 Oct. 21.

⁵⁷ National Research Council of the National Academies of Science. *Phthalates and Cumulative Risk Assessment The Task Ahead*, 2008. National Academies Press. Washington, D.C.

http://www.nap.edu/catalog.php?record_id=12528

⁵⁸ FFDCA §408(p)(1), 7 U.S.C. §346a(p)(1).

amphibians and fish.⁵⁹ Notable in the research is its structural similarity to thyroid hormones. This similarity, along with evidence of human exposures, “ have increased concern about the possible endocrine disrupting effects of triclosan.”⁶⁰

Recent studies have shown that triclosan can alter endocrine function in a variety of species. For example, one study sought to determine the effects of triclosan on pubertal development and thyroid hormone concentrations in the male Wistar rat. While the study demonstrated that triclosan exposure does not alter androgen-dependent tissue weights or onset of preputial separation, the study did determine that triclosan exposure significantly impacts thyroid hormone concentrations in male juvenile rats.⁶¹

The protocol for the study employed the Endocrine Disruptor Screening Program (EDSP) male pubertal protocol, administering triclosan daily by oral gavage until necropsy.⁶² The study clearly demonstrated that triclosan exposure in the juvenile male rat suppresses total serum thyroxine (T4) concentrations significantly and in a dose-dependent manner, leading the researchers to conclude:

Because triclosan is present in such a variety of personal care and household products, in the ecosystem, and in human body fluids, there is a serious concern for

⁵⁹Tatarzako, N., H. Ishibashi, K. Teshima, K. Kishi, and K. Arizono, *Effects of Triclosan on Various Aquatic Organisms*, Environmental Sciences 11(2), 133-40, (2004).
; Foran, C. M., Bennett, E. R., and Benson, W. H., *Developmental Evaluation of a Potential Non-Steroidal Estrogen: Triclosan*, Mar. Environ. Res. 50, 153-56 (2000); Ishibashi, H., Matsumura, N., Hirano, M., Matsuoka, M., Shiratsuchi, H., Ishibashi, Y., Takao, Y., and Arizono, K., *Effects of Triclosan on the Early Life Stages and Reproduction of Medaka *Oryzias Latipes* and Induction of Hepatic Vitellogenin*, Aquat. Toxicol. (Amst.) 67, 167-79 (2004); Veldhoen, N., Skirrow, R.C., Osachoff, H., Wigmore, H., Clapson, D.J., Gunderson, M. P., Van Aggelen, G., and Hebing, C.C., *The Bactericidal Agent Triclosan Modulates Thyroid Hormon-Associated Gene Expression and Disrupts Postembryonic Anuran Development*, Aquat. Toxicol. 80, 217-27 (2006).

⁶⁰ Kevin M. Crofton, Katie B. Paul, Michael J. DeVito, Joan M. Hedge, *Short-term in vivo Exposure to the Water Contaminant Triclosan: Evidence for disruption of Thyroxine* Environmental Toxicology and Pharmacology 24, 194-97 (2007).

⁶¹ Leah M. Zorrilla, Emily K. Gibson, Susan C. Jeffay, Kevin M. Crofton, Woodrow R. Setzer, Ralph L. Cooper, and Tammy E. Stoker, *The effects of Triclosan on Puberty and Thyroid Hormones in Male Wistar Rats*, Toxicological Sciences 107(1) 56-64 (2009).

⁶² *Id.* at 57.

adverse effects on human health. Although interspecies differences exist, effects on the thyroid of this magnitude, particularly T4, should be carefully evaluated due to thyroid hormone status of pregnant women on the future neuropsychological development of the child.⁶³

Another similar study, conducted by a research group that included three scientists from the EPA Office of Research and Development, performed experiments that “clearly demonstrate ... that triclosan decreases circulating concentrations of T₄ [thyroxine] in rats.”⁶⁴ These findings were deemed sufficiently strong that the researchers called for future research into triclosan’s effects on thyroid homeostasis and the relevance to humans.⁶⁵

Breast Cancer

Another important research area concerns the relation between triclosan usage and endocrine disruption leading to breast cancer. The breast is an endocrine-sensitive organ. So, in a modern environment of exposure to numerous endocrine-disrupting chemicals, it should not be a mystery that “disorders of the breast have become so widespread and that cancer in this organ has become the major cancer of women in the Western world.”⁶⁶ Indeed, although diet, smoking, alcohol and radiation have been identified as risk factors, “the main influence in the development of breast cancer remains lifetime exposure to

⁶³ *Id.* at 61-62.

⁶⁴ Kevin M. Crofton, Katie B. Paul, Michael J. DeVito, Joan M. Hedge, *Short-term in vivo Exposure to the Water Contaminant Triclosan: Evidence for Disruption of Thyroxine*, *Environmental Toxicology and Pharmacology* 24, 194-97 (2007).

⁶⁵ *Id.* at 196.

⁶⁶ P.D. Darbre, *Environmental Oestrogens, Cosmetics, and Breast Cancer*, *Best Practice & Research Chemical Endocrinology & Metabolism*, Vol. 20, No.1, pp. 121-43, at 122 (2006).

oestrogen.”⁶⁷ Cancer is caused by genetic changes in somatic cells of the breast that result in the loss of growth control in the affected cells.

The potential for breast cancer as a result of regular, direct application of xeno-oestrogens to the breast area has been the subject of significant research. Researchers have noted the rapidly-increasing, widespread use of cosmetics, some of which are applied around the breast, including underarm antiperspirant/deodorant products, body lotions, body sprays, moisturizing creams, tanning creams and suncare products. Further, many of these cosmetics are not rinsed off, as are shampoos or soaps, but are left on the skin so that accumulation, absorption through the dermis, and entry of the cosmetics into the tissues are considerably more likely.⁶⁸ Triclosan is known to be one of the substances in cosmetics that alter cell DNA and interfere with normal growth regulatory pathways (including oestrogen action).⁶⁹ Petitioners note that while approval and regulation of many of these triclosan applications comes within the ambit of the FDA, it is the *cumulative* impact of triclosan in the body (whatever the source and whatever the regulatory scheme) that poses these dangers.

⁶⁷ *Id.* See also, Lipworth, L., *Epidemiology of Breast Cancer*, European journal of Cancer Prevention 4, 7-30 (1995); Key, T.J, Verkasalo, P.K. U Banks, E., *Epidemiology of Breast Cancer*, The Lancet Oncology 2, 133-40 (2001).

⁶⁸ Darbre, *Environmental Oestrogens, Cosmetics, and Breast Cancer*, at 127.

⁶⁹ Ciniglia, C., Cascone, C., Giudice, R.L. et al., *Application of Methods for Assessing the Geno- and Cytotoxicity of Triclosan to C. ehrenbergii*, Journal of Hazardous Materials 122, 227-32 (2005); Adolfsson-Erici, M., Pettersson, M., Parkkonen, J., and Sturve, J. , *Triclosan, a Commonly Used Bactericide Found in Human Milk and in the Aquatic Environment in Sweden*, Chemosphere 46, 1485-89 (2002).

B. The Ubiquity of Triclosan Contributes to Bacterial Resistance in Antibiotic Medications and Antibacterial Cleansers

“The major driving force for development of resistance in bacteria to antimicrobial agents ... is the use of antimicrobials themselves.”⁷⁰ In the specific instance of triclosan, numerous recent studies provide substantial evidence that it promotes bacterial resistance to both antibiotic medications and antibacterial cleansers. This, of course, renders the antibiotics and the antibacterials ineffective for their intended use. Necessarily, users of the medications and cleansers are completely unaware of this non-functionality and are simply vulnerable to whatever consequences may ensue. At a minimum, they will have paid for a useless product. But in other instances, they may be left wide open to significant health risks.

Bacterial resistance may occur through mutation of the gene constitutions or the uptake of new genetic elements through horizontal gene transfer. Such resistance may cause multiple threats, since widespread use of the triclosan may not only result in bacteria that are resistant to triclosan but may also create resistance to other, including unrelated, antimicrobials and antibiotics (cross-resistance or co-resistance).

Further, while some have argued that the high concentration of triclosan found in articles like soap (for example, 2,500 µg/ml) is sufficient to kill even resistant bacterial strains, research has shown this is not necessarily true. One study examined triclosan activity in a commercial soap. Achievement of a 90% death rate in wild-type *E. coli* required exposure to 150 µg/ml of triclosan in soap for 2 hours at 37° C. Obviously, the

⁷⁰ Siamak P. Yazdankhah, Anne A. Scheie, E. Arne Høiby, Bjørn-Tore Lunestad, Even Heir, Tor Øystein Fotland, Kristine Naterstad, and Hilde Kruse, *Triclosan and Antimicrobial Resistance in Bacteria: An Overview*, *Microbial Drug Resistance*, Vol. 12, No. 2, 2006, at 83.

time, temperature and amount of the substance needed in the study far exceeded that for the average hand washing.⁷¹

Even in instances where triclosan may effectively inhibit bacteria in its principal application, potential problems still exist. The problem, particularly in triclosan-containing consumer products, is residues. These products usually leave residues (on kitchen and bathroom floors, countertops and other surfaces) and these residues will typically be diluted (in comparison to the product itself). At these “sublethal” concentrations, the residues can no longer inhibit or destroy bacterial action. In a similar vein, toothpastes often contain agents designed to increase the retention and effect of triclosan, promoting a more prolonged (but gradually decreasing) effect on the microflora. Important here is the fact that studies have shown that “at sublethal concentrations, triclosan inhibits a specific bacterial target, and several mechanisms of resistance to triclosan have been demonstrated.”⁷²

The problem, therefore, is the widespread use of triclosan—whatever the source and whatever agency has regulatory authority—giving rise to *increased and cumulative* exposure. And this should be distinguished from the more restricted, knowledgeable and careful use of it by medical professionals.⁷³ Just a few years ago, “only a few dozen products containing antibacterial agents were being marketed for the home. Now more than 700 are available.”⁷⁴ Triclosan’s broad-spectrum antibacterial properties have

⁷¹ Steward B. Levy, *Antibacterial Household Products: Cause for Concern*, Conference Presentation, *Emerging Infectious Diseases*, Vol. 7, No. 3 Supplement, June 2001, at 513.

⁷² *Triclosan and Antimicrobial Resistance in Bacteria: An Overview*, at 88.

⁷³ Siamak P. Yazdankhah, Anne A. Scheie, E. Arne Høiby, Bjørn-Tore Lunestad, Even Heir, Tor Øystein Fotland, Kristine Naterstad, and Hilde Kruse, *Triclosan and Antimicrobial Resistance in Bacteria: An Overview*, *Microbial Drug Resistance*, Vol. 12, No. 2, 2006.

⁷⁴ *Antibacterial Household Products: Cause for Concern*, at 512.

caused it to be utilized in an increasingly diverse and extensive range of uses. The implications of this broad, rapid increase for public health, however, are important:

There is a link between antibiotic and antibacterial resistance. Overuse or improper usage of antibacterials in the home can potentially enhance the selection process for resistance to these [antibacterial] products and to antibiotics.⁷⁵

While ordinary, healthy adults are indeed at risk because of triclosan-induced bacterial resistance, certain subpopulations are particularly vulnerable. These subpopulations include persons with impaired immune systems, infants and young children, and persons needing the benefit of antibiotics. One steadily rising and increasingly vulnerable subpopulation is that of persons recently returning home from hospitals and health care facilities who must continue to take antibiotics. It is well known that today hospital stays have become much shorter, both to lower hospital costs and to protect patients from problems such as nosocomial infections.⁷⁶ Patients returning home who continue to take antibiotics enter an environment rife with antimicrobial and other products containing triclosan. Hence, the danger of the antibiotics being rendered ineffective could be dangerously high.⁷⁷

EPA's RED states that there is currently "some research attempting to demonstrate a connection between antimicrobial resistance and antibiotic resistance in regard to triclosan, but the linkage has not been expressly proven."⁷⁸ But to the contrary, as discussed above, several peer-reviewed studies highlighting the concerns many

⁷⁵ Stuart B. Levy, *Antibiotic and Antiseptic Resistance: Impact on Public Health*, *Pediatric Infectious Disease Journal*, Vol. 19, No. 10, Oct. 2000, at S121.

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ EPA RED, p. 40.

scientists have with regard to triclosan's role in antibacterial resistance.

In spite of important research findings such as those described above, EPA chose to take an approach directly contrary to the precautionary principle. Thus, the agency requires that the connection between antimicrobial resistance and antibiotic resistance be “expressly proven,”⁷⁹ rather than taking action based on what is substantial and credible evidence of such a connection. Further, the serious nature of the threat posed in this area by triclosan merits more than having the agency merely “look into the issue,” or participate in the work of the Interagency Task Force on Antimicrobial Resistance⁸⁰ (Task Force). EPA even admits that “none of the goals [of the Task Force] are associated with a specific active ingredient.”⁸¹

C. Triclosan is Bioaccumulative and Poses an Immense Body Burden.

Because of its widespread usage and its properties, triclosan can be found in blood,⁸² urine,⁸³ and breast milk⁸⁴ in people around the world. And while consumers of triclosan-containing products retain the highest levels of the substance, even persons not using those products are vulnerable to exposure through food, water, and even household dust.⁸⁵ Indeed, one study, conducted by scientists at the Center for Disease Control and Prevention (CDC), found triclosan in 75 percent of the U.S. general population [a study of 2,517 urine samples using the NHANES method] and took particular note that the

⁷⁹ EPA RED, p. 40.

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² Allmyr, M. F. Harden, L.L. Toms, et al., *The Influence of Age and Gender on Triclosan Concentrations in Australian Human Blood Serum*, *Science of the Total Environment* 393, 162-67 (2008).

⁸³ Calafat, A.M, X Ye, L.Y. Wong et al., *Urinary Concentrations of Triclosan in the U.S. Population: 2003-2004*, *Environmental Health Perspectives* 116(3), 303-07 (2008).

⁸⁴ Allmyr, Mats et al., *Triclosan in Plasma and Milk from Swedish Nursing Mothers and Their Exposure Via Personal Care Products*, *Sci. Total Environ.* 372(1), 87-93 (2006).

⁸⁵ Canosa, P., I Rodriguez, E. Rubi, and R. Cela, *Determination of Parabens and Triclosan in Indoor Dust Using Matrix Solid-Phase Dispersion and Gas Chromatography with Tandem Mass Spectrometry*, *Analytical Chemistry* 79(4), 1675-81 (2007).

“high frequency of detection is most likely with daily use by the U.S. general population of [triclosan-containing] consumer products.”⁸⁶ As described throughout this Petition, given the dangers of each *individual* source of triclosan, the notion of a *cumulative* effect from all sources of this lipophilic (bioaccumulative in fatty tissues) substance truly makes clear the gravity of the health threat and the dire need for action.

EPA used data from the National Health and Nutrition Examination Survey (NHANES)⁸⁷ to determine population exposures to triclosan in its RED risk assessment. Petitioners take the position that NHANES data are useful only as a *supplement* to the risk assessment process. It is commendable that EPA has become receptive to using improved methods for carrying out its responsibilities with the use of real-world data. But NHANES data on triclosan exposure, standing alone, are insufficient to adequately determine human risk. Petitioners’ EPA Comments made the following significant points about NHANES methodology and capacity:

- *Urine Testing is Inadequate Because Triclosan Accumulates in Fatty Tissue*
 - Measurements of triclosan under NHANES are based on concentrations in spot urine samples.⁸⁸ Urine is not the appropriate fluid to *quantitatively* assess triclosan exposure, though it does provide useful *qualitative* information on population exposure to triclosan.

⁸⁶ Calafat, A.M, X Ye, L.Y. Wong et al., *Urinary Concentrations of Triclosan in the U.S. Population: 2003-2004*, Environmental Health Perspectives 116(3), 303-07 (2008); CDC. *Fourth National Report on Human Exposure to Environmental Chemicals*. Department of Health and Human Services Centers for Disease Control and Prevention (2009)

⁸⁷ NHANES data for triclosan can be found at <http://www.cdc.gov/nchs/nhanes.htm>.

⁸⁸ Risk Assessment, p. 27. See also, Calafat, A.M, X Ye, L.Y. Wong et al., *Urinary Concentrations of Triclosan in the U.S. Population: 2003-2004*, Environmental Health Perspectives 116(3), 303-07 (2008).

- Quantitative estimates require more detailed testing, including testing using breast milk, blood, and fat tissue sampling.
- *The Rapidly Growing List of Uses for Triclosan Renders the 2003-2004 NHANES Data Inadequate as a Basis for a Useful Assessment*
 - The current RED document is based on exposure information captured from the NHANES 2003-2004 data set. These data are simply unable to estimate the risk associated with the ever growing use of hundreds of triclosan-containing consumer products that have entered the market since 2003.
- *Food Contamination Must be Assessed by EPA*
 - EPA’s RED and its *Dietary Risk Assessment for Triclosan for the RED Process*⁸⁹ (Dietary Risk Assessment) concluded that “[n]one of the indirect food contact scenarios appear [sic] to exceed [the] Agency’s level of concern.”⁹⁰
 - EPA acknowledges, however, that “[e]xposures can occur where there is the possibility of indirect food migration (including paper/pulp use, use in ice-making equipment, adhesives, cutting boards, counter tops, and conveyer belts).”⁹¹
 - Yet, EPA admits that “no residue chemistry data based on [agency guidelines] were submitted nor was it requested.”⁹²

⁸⁹ EPA’s *Dietary Risk Assessment for Triclosan for the RED Process, August 11, 2008*(Dietary Risk Assessment).

⁹⁰ Dietary Risk Assessment. (unpaginated)

⁹¹ EPA RED, p. 15.

⁹² Dietary Risk Assessment.

- Petitioners believe that failure to perform a dietary risk assessment on triclosan- contaminated fish and shellfish ignores the evidence that triclosan is indeed readily absorbed via the human gastrointestinal tract and that this route of exposure could impact overall risk.⁹³ NHANES may capture many triclosan use patterns, but a complete evaluation of dietary risk from food and drinking water indirectly contaminated by triclosan is necessary.
- Total Reliance on NHANES Misses Health Impact on Users
 - NHANES does not specifically enable the evaluation of triclosan exposure and resulting residues in the body for those who use triclosan or triclosan-treated products. It instead identifies exposure to the general population, among a mixture of users and nonusers. Reliance solely on NHANES for the agency’s exposure assessment, therefore, provides inadequate protection of triclosan users.

1. Infants and Children Are Especially Vulnerable to Triclosan Reliance

Many parents are misled into thinking that antibacterial products are better to protect their children against germs and bacteria. However, children are especially put at risk when they are exposed to antibacterial toothpaste, soaps, baby creams, hand sanitizers and wipes that leave triclosan residues on their skin. This is especially so for products coming into contact with their hands, as this could ultimately result in oral exposures to the chemical as a direct result of hand –to-mouth activity. Babies' skin is

⁹³ Sandborgh-Englund et al. 2006. Pharmacokinetics of triclosan following oral ingestion in humans. J. Tox. and Environ. Health. Part A 69:1861-1873

also more permeable than an adult's,⁹⁴ leading to increased dermal absorption. As previously mentioned, triclosan is also found in breast milk and accumulates in the human body, directly exposing babies pre- and post-natal to concentrations of triclosan.

Studies have shown that children face unique hazards from chemical exposure.⁹⁵ They take in more chemical relative to their body weight than adults from the products to which they are exposed. Their developing organ systems often make them more sensitive to toxic exposure. The body of evidence in scientific literature shows that chemical exposure can adversely affect a child's neurological, respiratory, immune, and endocrine system, even at low levels.⁹⁶

2. Triclosan Poses Health Risks for Health Care Professionals

Triclosan even poses threats to health care professionals. In a 2009 report, Physicians for Social Responsibility announced the results of a study demonstrating that “health care professionals are exposed—through the workplace or in their personal lives—to a wide range of chemicals [including triclosan] known or suspected to cause health problems.”⁹⁷ *Hazardous Chemicals In Health Care* discussed the body burden and other threats posed by triclosan and concluded with several recommendations designed to protect health care professionals and the public.⁹⁸

⁹⁴ Silver, L. 2007. Baby Care Products. Prevention and Practice. *Learning and Developmental Disabilities Initiative*. Institute for Children’s Environmental Health (ICEH).

⁹⁵ US EPA, Office of the Administrator, Environmental Health Threats to Children, EPA 175-F-96-001, September 1996. See also: <http://www.epa.gov/pesticides/food/pest.htm>.

⁹⁶ Weiss, B., et al. 2004 April. “Pesticides,” *Pediatrics* 113(4): 1030-1036; National Research Council. 2000. Scientific frontiers in developmental toxicology and risk assessment. Washington, DC: National Academy Press; Physicians for Social Responsibility, The National Environmental Trust, and the Learning Disabilities Association of America. 2000. Polluting our future: Chemical pollution in the U.S. that affects child development and learning. http://www.net.org/health/tri_report.pdf (accessed 6/2/05).

⁹⁷ Report: *Hazardous Chemicals In Health Care*, Physicians for Social Responsibility, p. 23, October 9, 2009. (also available at <http://www.psr.org/assets/pdfs/hazardous-chemicals-in-health-care.pdf>).

⁹⁸ *Id.* at 22,-24 26-30.

3. Triclosan Usage Poses Health Risks for the Skin Because of its Toxicity

Numerous studies attest to the problems triclosan can cause for the skin. Reports observe such problems as dermatitis, or skin irritation,⁹⁹ photoallergic contact dermatitis,¹⁰⁰ eczematous rash, and even immunotoxic and neurotoxic reactions to the substance.¹⁰¹

D. Triclosan is Not Completely Removed from Wastewater and Sludge, Which May Result in Food Contamination

Triclosan products eventually enter the larger environment through wastewater and otherwise, and then adversely affect human, animal and other environmental resources. Because 95% of triclosan use is in consumer products that are disposed of down residential drains, sewage and wastewater provide a prime medium of triclosan entry into the larger environment. As explained below, even where it does reach wastewater treatment plants (as some runoff from both residential and commercial sites streams directly into the environment), triclosan still may re-enter the environment and pose health threats.

A major source of triclosan in waterways is sewage sludge. Triclosan accumulates in sewage sludge from municipal wastewater treatments.¹⁰² The sewage sludge is spread on land, and triclosan leaches down through the soil and runs off into surface water from

⁹⁹ Strer, E., K.J. Koh, and L. Warren, *Severe Contact Dermatitis as a Result of an Antiseptic Bath Oil*, Australasian Journal of Dermatology 45(1), 73-75 (2004).

¹⁰⁰ Durbize, E., M. Vigan, E. Puzenat, et al., *Spectrum of Cross-photosensitization in 18 Consecutive Patients with contact Photoallergy to Keptoprofen: Associated Photoallergies to Non-benzophenone-containing Microbes*, Contact Dermatitis 48(3), 144-49 (2003).

¹⁰¹ Stafford, J., *Germ Warfare*, Voices, Health and Fiction, C2-C3 (May 5, 1997).

¹⁰² Heidler, J and RU Halden, *Mass Balance Assessment of Triclosan Removal During Conventional Sewage Treatment*, Chemosphere 66: 362-69, (2007)

the fields.¹⁰³ Triclosan has been shown to persist in the runoff from treated fields for as long as 266 days after biosolid application and to persist in the sediment for long periods of time.¹⁰⁴ EPA, in its *Targeted National Sewage Sludge Survey Report*, presented the results of certain studies, specifically, the *Targeted National Sewage Sludge Survey Sampling and Analysis Technical Report ("Technical Report")*, and the *Targeted National Sewage Sludge Survey Statistical Analysis Report ("Statistical Report")*. Triclosan was detected in 79 of a total of 84 sludge samples used in the survey, and both its minimum and maximum observed dry-weight concentrations were significant.¹⁰⁵ Wastewater, in fact, is “the principal pathway of [triclosan] contamination” in estuarine sediments.¹⁰⁶ As discussed below, the health and environmental implications of these characteristics are significant.

The EPA RED acknowledged that “triclosan has been detected in natural waterways,” and thus it was “prudent to conduct a qualitative risk assessment using surface water monitoring data.”¹⁰⁷ Therefore, the agency conducted an assessment using various studies and methods, including a Tier 1, *Down-the-Drain (DTD) module* and a *Probabilistic Dilution Model (PDM)*. In doing so, EPA found that “triclosan may be susceptible to biodegradation based on the presence of methyl-triclosan following

¹⁰³ Lapen, D.R., E. Topp, C.D. Metcalfe, et al., *Pharmaceutical and Personal Care Products in Tile Drainage Following Land Application of Municipal Biosolids*, Science of the Total Environment, 2008. Topp, E., S.C. Monteiro, A. Beck, et al., *Runoff of Pharmaceuticals and Personal Care Products Following Application of Biosolids to an Agricultural Field*, Science of the Total Environment, 296: 52-59, 2008.

¹⁰⁴ Topp, et al. Wilson, B., J. Zhu, M. Canwell, and C.R. Olsen, *Short-Term Dynamics and Retention of Triclosan in the Lower Hudson River Estuary*, Marine Pollution Bulletin (2008).

¹⁰⁵ See, Technical Report, Table 12, p 41..

¹⁰⁶ Todd R. Miller, Jochen Heidler, Steven N. Chillrud, Amelia DeLaquil, Jerry C. Ritchie, Jana N. Milhalic, Richard Bopp, and Rolf U. Halden, *Fate of Triclosan and Evidence for Reductive Dechlorination of Triclocarban in Estuarine Sediments*, Environ. Sci. Technol. 42(12), 4570-4576, 2008.

¹⁰⁷ EPA RED, p. 28.

wastewater treatment.”¹⁰⁸ Interestingly, for a number of areas of health and environmental impacts, EPA reached no ultimate conclusion. Rather it shifted the responsibility for (and the control over) to applicants for reregistration at a later date:

At this time this testing is not required for triclosan, but is dependent upon the results of environmental modeling and monitoring which are required to support reregistration of triclosan.¹⁰⁹

In this regard, it is noteworthy that on October 8, 2008, EPA proposed revisions to its data requirements for antimicrobial pesticides under FIFRA, in conjunction with its wider effort to update and streamline its data requirements for all pesticides.¹¹⁰ Among the new requirements are certain ones intended for use in a screening-level assessment on the fate of antimicrobials with the potential to reach a wastewater treatment plant. These products would include “down-the-drain” products as well as microbiocides used in industrial process and water systems. The proposal has been viewed favorably by many concerned agencies.¹¹¹

In other areas, EPA admitted to considerable uncertainty about ecological exposure and risk.¹¹² Petitioners submit that these scenarios call out for application of the precautionary principle. That is, in the face of credible evidence of health and environmental threats, a regulatory agency must not allow continued use of a suspect substance until scientific study and evidence clearly demonstrate the safety of that substance.

¹⁰⁸ *Id.* at 29.

¹⁰⁹ *Id.* at

¹¹⁰ *Data Requirements for Antimicrobia Pesticides*. 73 Fed. Reg. 59382 (Oct. 8, 2008).

¹¹¹ See, e.g., Comments of the National Association of Clean Water Agencies, the California Association of Sanitation Agencies, and the San Francisco Department of the Environment.

¹¹² EPA RED at 31-33.

A study by researchers from the U.S. Geological Survey, using five newly developed analytical methods, sought to measure concentrations of 95 organic wastewater contaminants (OWCs). The study took water samples from a network of 139 streams across 30 states during 1999 and 2000.¹¹³ Sampling site selection was biased in favor of streams susceptible to contamination, such as waters downstream of intense urbanization and livestock production. Results revealed that triclosan was one of the 30 most frequently detected OWCs.¹¹⁴ The researchers observed:

Surprisingly, little is known about the extent of environmental occurrence, transport, and ultimate fate of many synthetic organic chemicals after their intended use, particularly hormonally active chemicals, personal care products and [certain] pharmaceuticals.¹¹⁵

Subsequently, researchers have expanded the base of knowledge about triclosan's presence and impact in the environment. One study evaluated a full-scale activated sludge facility (one representative of most U.S. plants) to determine its effectiveness in controlling triclosan. The study concluded that "the beneficial reuse of digested municipal sludge as agricultural fertilizer represents a mechanism for the reintroduction of substantial amounts of TCS [triclosan] into the environment."¹¹⁶ Thus, not only is triclosan present in the environment initially, but it remains in the environment even after the wastewater treatment process.

¹¹³ Dana W. Kolpin, Edward T. Furlong, Michael T. Meyer, E. Michael Thurman, Steven D. Zaugg, Larry B. Barber, Herbert T. Buxton, *Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance*, Environ. Sci. Tech. 36, 1202-1211, at 1202, (2002).

¹¹⁴ *Id.* at 1207 (Fig. 2), 1208.

¹¹⁵ *Id.*

¹¹⁶ Jochen Heidler, Rolf U. Halden, *Mass Balance Assessment of Triclosan Removal During Conventional Sewage Treatment*, Chemosphere 66, 362-369, at 368, (2007).

A study of triclosan in Swiss water bodies found high concentrations of the substances in several lakes and rivers, as well as lower levels of methyl triclosan, a by-product. (Methyl triclosan is more lipophilic than triclosan and is thus more bioaccumulative.¹¹⁷) Generally, therefore, triclosan is present in a large number of waterways, and thus humans and animals are vulnerable to its effects. Accordingly, there are numerous potential adverse impacts.

E. EPA Failed to Address Major Degradates

As the following discussion shows, EPA has failed to address adequately the subject of the health and environmental threats posed by major degradates of triclosan.

Dioxins are highly carcinogenic that can cause immune system compromise, decreased fertility, altered sex hormones, miscarriage, birth defects, and cancer. It can be present or be formed in many ways, including as a synthesis impurity of triclosan¹¹⁸ during the manufacture of many products, and upon the incineration of triclosan.¹¹⁹

Researchers who added triclosan to river water and shined ultraviolet light on the water found that between one and twelve percent of the triclosan was converted to dioxide in the water. This suggests that sunlight could transform triclosan into dioxin naturally.¹²⁰ Further, triclosan-tainted water at water treatment plants pose the danger of sunlight converting chlorinated triclosan into highly toxic forms of dioxins. Yet another potential

¹¹⁷ Anton Lindstrom, Ignaz J. Buerge, Thomas Poiger, Per-Anders Bergqvist, Markus D. Müller, and Hans Rudolf Buser, *Occurrence and Environmental Behavior of the Bactericide Triclosan and its Methyl Derivative in Surface Waters and in Wastewater*, Environ. Sci. Technol. 36, 2322-2329 (2002).

¹¹⁸ Menoutis, J. and A.I. Parisi, *Triclosan and its impurities*, Triclosan Review Series, Quantex Laboratories, Inc., available at <http://www.quantexlabs.com/triclosan.htm>.

¹¹⁹ Kanetoshi, A., H. Ogawa, E. Katsura, H. Kaneshima, and T. Miura, *Formation of Polychlorinated Dibenzo-p-dioxins Upon Combustion of Commercial Textile Products Containing 2,4,4-Trichloro-2-Hydroxydiphenyl Ether*, Journal of Chromatography A 454, 145-55 (1988).

¹²⁰ Latch, D.E., J.L. Packer, W.A. Arnolda, and K. McNeill, *Photochemical Conversion of Triclosan to 2,8-Dichlorodibenzo-p- in aqueous solution*, Journal of Photochemistry and Photobiology A: Chemistry 158 (1), 63-66 (2000).

danger is that exposure of sunlight to solid-state triclosan, such as on commercial textile products, causes formation of small amounts of dioxin.¹²¹

A study by researchers at the Virginia Polytechnic Institute and State University found that triclosan reacts with free chlorine in tap water to form a number of chlorinated triclosan intermediates, including 2,4 dichlorophenol, which photochemically generates highly chlorinated dioxins. These are some of the most toxic forms of dioxin. Those researchers found that these chlorinated intermediates can be formed in kitchen sinks simply by using dishwashing liquid containing triclosan.¹²² Additionally, it should be noted that degradate 2,4 dichlorophenol is a noted CWA priority pollutant, as well as a potential endocrine disruptor.

Some of the same studies concluding that triclosan reacts with tap water under dishwashing conditions to form dioxins also found that this combination also produces significant quantities of chloroform gas.¹²³ Chloroform has been classified as a probable human carcinogen.¹²⁴

F. Triclosan is Highly Toxic to Various Forms of Algae and This Can Cause Ecological Damage

Triclosan can have detrimental effects on aquatic ecosystems. Triclosan has been found to be highly toxic to different types of algae.¹²⁵ Triclosan effluents affect both the

¹²¹ Kanetoshi, A., H. Ogawa, E. Katsura, H. Kaneshima, and T. Miura, *Formation of Polychlorinated Dibenzop-dioxins Upon Combustion of Commercial Textile Products Containing 2,4,4-Trichloro2-Hydroxydiphenyl Ether*, *Journal of Chromatography A* 454, 145-55 (1988).

¹²² Rule, K.L., V.R. Ebbett, and P.J. Vikesland, *Formation of Chloroform and Chlorinated Organics by Free-Chlorine-Mediated Oxidation of Triclosan*, *Environ. Sci. Technol.*, April 2, 2005.

¹²³ *Ibid.*

¹²⁴ EPA, Office of Pesticide Programs, *List of Chemicals Evaluated for Carcinogenic Potential*, updated July 19, 2004.

¹²⁵ Tatarzako, N., H. Ishibashi, K. Teshima, K. Kishi, and K. Arizono, *Effects of Triclosan on Various Aquatic Organisms*, *Environmental Sciences* 11(2), 133-40, (2004).

structure and the function of algal communities in stream ecosystems.¹²⁶ Because algae are the first-step producers in aquatic ecosystems, high levels of triclosan discharged into the environment may cause widespread negative consequences, including “the possible destruction of the balance of the ecosystem.”¹²⁷ The risks are especially high immediately downstream from wastewater treatment plants.¹²⁸

Because of its lipophilic nature and resistance to degradation, triclosan in waterways is readily available for absorption and bioaccumulation by aquatic organisms in the environment.¹²⁹ Researchers in Sweden found high levels of triclosan were present in the bile of fish that were placed in cages downstream of sewage treatment works in Sweden.¹³⁰ Methyl triclosan, a transformation product of triclosan, has been found in fish.¹³¹ Although little is known about the effects on fish, triclosan has been found to be highly toxic to Japanese medaka fish in their early life stages, and it may cause weak endocrine disruption as well.¹³²

The EPA RED observed that in aquatic environments, “triclosan is expected to absorb to [sic] suspended solids and sediments and may bioaccumulate...posing a

126 Wilson, B.A., V.H. Smith, F. deNoyelles Jr., and C.K. Larive, Effects of Three Pharmaceutical and Personal Care Products on Natural Freshwater Algal Assemblages, *Environmental Science and Technology* 37(9), 162A-164A (2003).

127 Tatarzako, N., H. Ishibashi, K. Teshima, K. Kishi, and K. Arizono, Effects of Triclosan on Various Aquatic Organisms, *Environmental Sciences* 11(2), 133-40, (2004).

128 Reiss, R., N. Mackay, C. Habig, and J. Griffin, An Ecological Risk Assessment for Triclosan in Lotic Systems Following Discharge from Wastewater Treatment Plants in the United States, *Environmental Toxicology and Chemistry* 21 (11), 2483-2492 (2002).

129 Tatarzako, N., H. Ishibashi, K. Teshima, K. Kishi, and K. Arizono, Effects of Triclosan on Various Aquatic Organisms, *Environmental Sciences* 11(2), 133-40, (2004).

130 *Ibid.*

131 Balmer, M. E., T. Poiger, C. Droz, K. Romanin, et al., Occurrence of Methyl Triclosan, a Transformation Product of the Bactericide Triclosan, in Fish from Various Lakes in Switzerland, *Environmental Science and Technology* 38, 390-95 (2004).

132 Ishibashi, H., N. Matsumura, M. Hirano, M. Matsuoka, et al., Effects of Triclosan on the Early Life Stages and Reproduction of Medake *Oryzias Latipes* and Induction of Hepatic Vitellogenin, *Aquatic Toxicology* 67, 167-79 (2004).

concern for aquatic organisms.¹³³ In fact, its own qualitative environmental risk assessment determined that levels of concern “were exceeded for aquatic plants.”¹³⁴ But, as noted in this Petition’s discussion of wastewater treatment, EPA’s analysis was incomplete. In some areas, no conclusions were drawn and further testing was left to registrants. In other instances, EPA admitted that the studies and data were incomplete, but the agency declined to apply the precautionary principle.¹³⁵

G. Efficacy

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.

As discussed in Section II (B) of this Petition, development of bacterial resistance to triclosan itself from triclosan use and exposure render the substance ultimately ineffective for the purposes claimed. But further, numerous studies demonstrate that triclosan, in its initial use, confers no real added benefits to consumer users. One study concludes there are no added health benefits (that is, none beyond those provided by soap and water) for consumer use of triclosan. Said the study:

The results of our review call into question the marketing of soaps containing triclosan as a product providing efficacy *beyond* the use of plain soap in the community setting ... Current findings warrant actions by the FDA for evaluating consumer product advertising claims.¹³⁶

¹³³ RED, p. 28-29.

¹³⁴ RED, p. 31.

¹³⁵ See, e.g., EPA RED, pp. 30-31.

¹³⁶ Aiello, A.E., E.L. Larson, and S.B. Levy, *Consumer Antibacterial Soaps: Effective or Just Risky?*, *Clinical Infectious Diseases* 45, 137-47 (2007); Siamak P. Yazdankhah, Anne A. Scheie, E. Arne Høiby, Bjørn-Tore Lunestad, Even Heir, Tor Øystein Fotland, Kristine Naterstad, and Hilde Kruse, *Triclosan and Antimicrobial Resistance in Bacteria: An Overview*, *Microbial Drug Resistance*, Vol. 12, No. 2, 2006.

As early as 2000, the American Medical Association (AMA) expressed doubt about the efficacy of antimicrobial ingredients in consumer products. The AMA Council on Scientific Affairs stated that “[n]o data exist to support their efficacy when used in such products or any need for them.”¹³⁷ Further, while lack of efficacy is important, what rendered this lack of evidence concerning was that “increasing data now suggest growing acquired resistance to these commonly used antimicrobial agents.”¹³⁸ Especially for these reasons the AMA Council recommended that:

- The FDA “expedite its regulation of the use in consumer products of antimicrobials for which acquired resistance has been demonstrated;”
- The AMA “monitor the progress of the current FDA evaluation of the safety and effectiveness of antimicrobials for consumer use;” and
- The AMA encourages “continued research” on the use of common antimicrobials in consumer products and its impact on the *major health problem of antimicrobial resistance*.”¹³⁹

These and other influential expressions set forth a clear and sound mandate for action by the EPA.

H. Organizational Decisions Criticizing, Condemning or Rejecting Triclosan Usage

As the scientific evidence against widespread triclosan usage mounts, numerous organizations have criticized, condemned or rejected that substance in formal and definitive ways. These organizations run the gamut, including governmental units,

¹³⁷ American Medical Association, 2000 Annual Meeting, *Reports of the Council on Scientific Affairs*, at 4 (2000).

¹³⁸ *Id.*

¹³⁹ *Ibid.*

corporate entities, research societies and professional associations. The following are prominent examples:

Corporate Retreats from Triclosan

In March 2009, Ciba, the creator of triclosan, formally filed with the EPA a request for the “voluntary cancellation of the registrations for triclosan regulated by the” EPA.¹⁴⁰ This request seeks to cancel the use of Ciba triclosan “as an antimicrobial for the protection of polymers/plastics and textiles.”¹⁴¹ The company decided “*to pull out of ancillary markets such as household items.*” In taking this step, the company sought to “differentiate Ciba triclosan products, which [it claims] are supported by an exhaustive database of safety research, from the proliferation of triclosan made by other manufacturers.”¹⁴²

Petitioners query whether this decision to “differentiate” Ciba triclosan products is *actually* a reflection of the growing scientific evidence *against* many of the varied and pervasive uses of triclosan. After all, Ciba could well have “differentiated” those now-abandoned products through the traditional methods of marketing, advertising and informational campaigns about their safety and effectiveness—as it has attempted to do with the products it continues to produce. At a minimum, such a substantial strategic change¹⁴³ must be viewed against the background of the growing scientific consensus and public concern about triclosan usage. Additionally, and necessarily, the rationale for

¹⁴⁰ EPA, Notice of Receipt of Requests To Voluntarily Cancel Certain Pesticide Registrations, Docket No. EPA-HQ-OPP-2007-0513; FRL-8410-6, Federal Register: April 22, 2009, Volume 74, Number 76.

¹⁴¹ Ciba website, available at <http://www.ciba.com/ind-pc-triclosan-prod-safe.htm>.

¹⁴² *Id.* (Emphasis added)

¹⁴³ See, 2008 Ciba Annual Report, Notes to Consolidated Financial Statements, Note 4, Acquisitions and discontinued operations, available at <http://www.ciba.com/2008-ciba-annualreport.pdf>, observing that Ciba sold its Textile Effects business in 2006 and sold its Performance Polymers business in 2000. The transactions involved significant restructuring costs.

the decision is nothing less than a serious indictment against those “other manufacturers” to which Ciba refers.

Decisions of Other Governmental Entities about Triclosan

1. European Commission, Scientific Committee on Consumer Products.

Petitioners query whether Ciba’s decision was influenced by a recent opinion, adopted just two months earlier, by the European Commission's Scientific Committee on Consumer Products¹⁴⁴ (SCCP Opinion). The SCCP Opinion found that “continued use of triclosan as a preservative at the current concentration limit of maximum 0.3% in all cosmetic products is not safe for the consumer because of the magnitude of the aggregate exposure.”¹⁴⁵ That opinion also determined that triclosan usage of certain “leave-on products (e.g. body lotions) and in mouthwashes is not considered safe for the consumer due to the resulting high exposures.”¹⁴⁶

Finally, although the SCCP Opinion did not find triclosan use unsafe, at a maximum concentration of 0.3%, in toothpastes, hand soaps, body soaps/shower gels and deodorant sticks, face powders and blemish concealers, it readily admitted a significant qualification to this finding:

Importantly, before a final conclusion on the safety of triclosan in cosmetic products can be reached, the potential development of resistance

¹⁴⁴ European Commission, Health & Consumer Protection Directorate-General, Scientific Committee on consumer Products, *Opinion on Triclosan*, COLIPA No. P32, SCCP/1192/08, adopted at 19th plenary of 21 January 2009.

¹⁴⁵ *Id.* at p. 123.

¹⁴⁶ *Id.*

to triclosan and cross-resistance by certain micro-organisms must be assessed. This aspect is not covered in this document....¹⁴⁷

Thus, the SCCP withheld a decision on triclosan's dangers in these areas pending further research on the substance's propensity to promote bacterial resistance and cross-resistance. Petitioners refer to the discussion in Section II (B) of this Petition citing the substantial and compelling evidence confirming the reality, and thus the threat, of such resistance.

2. California Environmental Protection Agency, Office of Environmental Health Hazard Assessment.

The Ciba decision might also reflect certain deliberations on the dangers of triclosan usage by the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA). In March, 2009, OEHHA included triclosan among 38 chemicals to be reviewed by the state Carcinogen Identification Committee (CIC) for potential "listing" under the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). Although Ciba recommended "against accepting triclosan" for inclusion in the process potentially leading to a listing,¹⁴⁸ OEHHA nonetheless included triclosan in its prioritization groupings.¹⁴⁹

3. British Royal Commission on Environmental Pollution

Yet another significant and relevant decision is one by the British Royal Commission on Environmental Pollution. (British Royal Commission) In 2003, the

¹⁴⁷ Id. Also, the SCCP Opinion did not assess inhalation exposure to triclosan from spray products (e.g. deodorants). Id.

¹⁴⁸ See, Letter from Lisa Navarro, of Ciba, to OEHHA, May 4, 2009, available at http://oehha.ca.gov/prop65/public_meetings/052909coms/triclosan/CibaCorpTriclosan.pdf.

¹⁴⁹ See, OEHHA, "Meeting Synopsis and Slide Presentations Carcinogen Identification Committee Meeting Held on May 29, 2009", available at http://www.oehha.ca.gov/prop65/public_meetings/cic060509.html.

British Royal Commission Recommended a regulatory ban on synthetic chemicals. What is significant about this decision is the application--in stark contrast to EPA's complete rejection--of the "precautionary principle." The British Royal Commission stated:

We recommend that where synthetic chemicals are found in elevated concentrations in biological fluids such as breast milk and tissues of humans, regulatory steps be taken to remove them from the market immediately.¹⁵⁰

Thus, the British Royal Commission's recommendation was an exemplary application of the precautionary principle, as it recommended "that action be taken to reduce risk from chemicals in the face of uncertain but suggestive evidence of harm."¹⁵¹

Decisions of Professional Associations

The following examples show that some professional associations are stepping forward to express formally their serious reservations about triclosan usage.

1. American Medical Association

As discussed in Section II (G) of this Petition, the American Medical Association's Council on Scientific Affairs stated its significant concerns about the efficacy of triclosan. That body recommended several protective steps aimed at acquiring additional scientific knowledge while protecting public health and safety.

2. Canadian Medical Association

¹⁵⁰ Royal Commission on Environmental Pollution, Twenty-fourth Report, *Chemicals in Products: Safeguarding the Environment and Human Health*, June 3, 2003. The **Royal Commission on Environmental Pollution (RCEP)** is an independent standing body established in 1970 to advise the Queen, Government, Parliament, the devolved administrations and the public on environmental issues. Although funded by the Department for Environment, Food and Rural Affairs, the Royal Commission is independent of Government Departments.

¹⁵¹ Pesticide Action Network International (PAN), *Briefing Paper on the Precautionary Principle*, 09/14/06, available at http://www.panap.net/uploads/media/PAN_precaution_14_Sep_06.pdf (PAN Paper).

In 2009, the Canadian Medical Association, at its Annual Meeting, Adopted the following Resolution:

The Canadian Medical Association calls upon the federal government to ban the sale of household antibacterial products due to the risk of bacterial resistance and to recognize that soap and alcohol-based solutions are as effective in preventing household infection.¹⁵²

3. Physicians for Social Responsibility

In a 2009 report, Physicians for Social Responsibility announced the results of a study demonstrating that “health care professionals are exposed—through the workplace or in their personal lives—to a wide range of chemicals [including triclosan] known or suspected to cause health problems.”¹⁵³ *Hazardous Chemicals In Health Care* concluded with several recommendations designed to protect health care professionals and the public.¹⁵⁴

The foregoing discussion illustrates that the momentum of the concern about the dangers of triclosan is growing steadily and rapidly. Further, both substantial corporate and governmental actors are attesting to the seriousness and the soundness of that concern through their actions.

¹⁵² Canadian Medical Association Resolution No. 74, Resolutions Adopted at General Council, 17-19 August 2009, 142nd Annual Meeting Saskatoon, SK (also available at http://www.cma.ca/index.cfm/ci_id/89632/la_id/1.htm).

¹⁵³ Report: *Hazardous Chemicals In Health Care*, Physicians for Social Responsibility, p. 23, October 9, 2009. (also available at <http://www.psr.org/assets/pdfs/hazardous-chemicals-in-health-care.pdf>).

¹⁵⁴ *Id.* at 26-30.

Conclusion

Petitioners have demonstrated in this Petition that a substantial body of scientific studies, reports and other sources support the position that the constantly-expanding, pervasive and diverse uses of triclosan pose an actual and imminent threat to human health and the environment. Therefore, triclosan usage in EPA-approved applications is unsafe and ineffective, in violation of FIFRA and the FFDCA, and the agency must take such action as required by law to bring its regulation of triclosan into compliance with these statutes and other relevant statutes, including CWA, SDWA, and ESA. In the interests of the protection of human health and the overall environment that supports it, Petitioners request that the EPA ban triclosan and apply in additional, ancillary remedies provided for in federal law.

Respectfully Submitted

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January 14, 2010

Appendix A

Petition Signatories

1. Beyond Pesticides
2. Food and Water Watch
3. Alaska Community Action on Toxics
4. American Federation of Teachers
5. Ban Pesticides in Ulster County
6. Bernhoft Center for Advanced Medicine
7. Beyond Pesticides Ohio
8. Biological Pest Management
9. Black Warrior Riverkeeper
10. Blue Ridge Environmental Defense League
11. Breast Cancer Fund
12. BURNT
13. California Safe Schools
14. Californians for Alternatives to Toxics
15. Cancer Awareness Coalition
16. Cape Fear COASTKEEPER®
17. Center for Biological Diversity
18. Center for Environmental Health
19. Chemical Sensitivity Disorders Association
20. Choctawhatchee Riverkeeper
21. Citizens Campaign for the Environment
22. Citizens for Reform of Pesticide Spraying
23. Clean Production Action
24. Concerned Citizens for Clean Air
25. Deirdre Imus Environmental Center for Pediatric Oncology
26. Donaldson Farms
27. Ecological Health Organization
28. Ecology Center
29. Environment and Human Health, Inc.
30. Environmental Working Group
31. Equal Exchange
32. Farmworker Association of Florida
33. Fearless Fund
34. Fluoride Action Network
35. Friends of Hurricane Creek
36. Galveston Baykeeper
37. Grass Roots the Organic Way (GROW)
38. Grassroots Environmental Education
39. Great Neck Breast Cancer Coalition
40. Green Science Policy Institute
41. Greenpeace US
42. Healthy Building Network

43. Healthy Child Healthy World
44. HELP New Paltz (HEalthy Lawns Project)
45. Hilltown Anti-Herbicide Coalition
46. Huntington Breast Cancer Action Coalition
47. Informed Choices
48. Informed Green Solutions, Inc.
49. Kids for Saving Earth
50. Maryland Pesticide Network
51. Massachusetts Breast Cancer Coalition
52. National Center for Environmental Health Strategies
53. National Toxic Encephalopathy Foundation
54. Natural Resources Council of Maine
55. Neuse RIVERKEEPER® Foundation
56. New Jersey Environmental Federation
57. No Spray Nashville
58. Oregon Toxics Alliance
59. Osborne Organics
60. Parents for a Safer Environment
61. Pesticide Action Network North America
62. Pesticide Awareness and Alternatives Coalition
63. Pesticide Watch
64. Physicians for Social Responsibility
65. PODER
66. Warren Porter, Ph.D., University of Wisconsin-Madison
67. Protect All Children's Environment
68. Rochesterians Against the Misuse of Pesticides
69. SaferBuilding
70. Safer Pest Control Project
71. Satilla Riverkeeper
72. Shenandoah Riverkeeper
73. Sustainable Agriculture and Pesticide Policy (SAPP) Group
74. Sustainability Institute at Molloy College
75. Terry Shistar, Ph.D.
76. TEDX (The Endocrine Disruption Exchange)
77. Tualatin Riverkeeper
78. Toxic Free North Carolina
79. Virginia Eastern SHOREKEEPER
80. Western Lake Erie Waterkeeper
81. Women's Environmental Institute
82. Women's Voices for the Earth

Appendix B
Organizations Supporting December 2008 Comments on the
Proposed Rule: Triclosan; Reregistration Eligibility Decision
(EPA-HQ-OPP-2007-0513-0053)

Action Now
Alaska Community Action on Toxics
American Bird Conservancy
Beyond Pesticides Ohio
Breast Cancer Fund
BURNT
California Safe Schools
Californians for Alternatives to Toxics
Center for Environmental Health
Chemical Sensitivity Disorders Association
Citizens Campaign for the Environment
Ecology Center
Environmental Health Network
Environment and Human Health, Inc.
Grass Roots the Organic Way (GROW)
Greenpeace US
Healthy Building Network
Healthy Child Healthy World
Maryland Pesticide Network
National Center for Environmental Health Strategies
Natural Resources Council of Maine
Natural Resources Defense Council
No Spray Nashville
Northwest Coalition for Alternatives to Pesticides
Oregon Toxics Alliance
Pesticide Action Network North America (PANNA)
Pesticide Watch
Warren Porter, PhD, University of Wisconsin
Protect All Children's Environment
Safer Pest Control Project
San Francisco Baykeeper
Sierra Club
TEDX (The Endocrine Disruption Exchange)
Women's Environmental Institute
Women's Voices for the Earth