

AMENDED CITIZEN PETITION TO THE UNITED STATES  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

Division of Dockets Management  
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Beyond Pesticides )  
*Petitioners,* )  
Filed With: )  
Margaret Hamburg )  
In her official capacity as )  
Commissioner )  
Food and Drug Administration )

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## AMENDED CITIZEN PETITION FOR A BAN ON TRICLOSAN

### I. Preliminary Statement

Petitioners Beyond Pesticides and Food & Water Watch, acting through counsel and supported by the organizations listed in Appendix A, hereby submit this Amended Citizen Petition<sup>1</sup> (Amended Petition). As in the original Petition submitted October 25, 2005, Petitioners are requesting that the Food and Drug Administration (FDA) ban the use of triclosan for certain applications on the basis that its use in those applications violates the Federal Food, Drug and Cosmetics Act (FFDCA or Act). Specifically, the Petitioners assert that triclosan usage in these applications, both as a “cosmetic” and as a “drug,” is unsafe and ineffective for humans and animals in that such usage is “adulterated,” “misbranded” and otherwise in violation of the FFDCA.

Petitioners submit this Amended Petitions in a representative capacity as organizations seeking to protect the public health of citizens adversely affected by triclosan usage and to protect overall related ecosystem and environmental values. Further, Petitioners submit this Amended Petition under the authority of, and in accordance with, the First Amendment to the United States Constitution,<sup>2</sup> the Administrative Procedure Act,<sup>3</sup> and applicable FDA regulations.<sup>4</sup> FDA is being

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<sup>1</sup> 21 CFR §10.30 (g) provides that a” petitioner may supplement, amend or withdraw a petition in writing ...at anytime [until the agency rules on the petition].” Additionally, this Amended Petition responds to a specific request for clarification from FDA. See, Letter, dated April 19, 2006, to Jay Feldman of Beyond Pesticides, from Dr. Steven K. Galson, Director, Center for Drug Evaluation and Research, FDA, on file with Petitioners and placed in the Docket..

<sup>2</sup> U.S. Const. Amend. I, recognizing the “right of the people ... to petition the Government for a redress of grievances.”

<sup>3</sup> 5 U.S.C. §553(c), requiring each agency to give “interested persons” the “right to petition for the issuance, amendment, or repeal of a rule.”

<sup>4</sup> 21 C.F.R., Part 10.

requested to take action based on, *inter alia*, FFDCAs §§ 201, 301, 401, 402, 403, 403A, 406, 408, 501, 502, 505, and 701.

Triclosan (5-chloro-2-(2,4-dichlorophenoxy)phenol) is a potent antibacterial and antifungal compound that is widely used as an antibacterial agent, bactericide, disinfectant, and fungicide. It is regulated by both the FDA and the United States Environmental Protection Agency (EPA). The FDA-registered uses include hand soaps, toothpastes, deodorants, laundry detergents, fabric softeners, facial tissues, antiseptics for wound care, and medical devices. Continually-emerging scientific knowledge now demonstrates that past triclosan registration decisions were flawed. That is, the underlying registration processes lacked adequate and complete data on the ineffectiveness and the risks associated with FDA-approved uses of the substance.

#### *The Petitioners' Major Claims*

At the heart of this Amended Petition is the Petitioners' serious concern, based on a substantial body of scientific studies, reports and other sources, that the constantly-expanding, pervasive and diverse uses of triclosan pose an actual and imminent threat to human health and the environment. As set out in this Amended Petition, this concern includes the following key areas of impact:

- 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;

- 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;
- Endocrine disruption is another potential result of triclosan bioaccumulation in the body. This effect, in turn, poses serious threats to thyroid and other organ functions, and it can also influence the development of cancer;
- 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;
- 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;

- It can be highly toxic to different types of algae, thus creating both specific threats as well as potential destruction of larger ecosystem balance.
- Finally, numerous scientific studies and reports indicate that triclosan is not effective for many of its major intended benefits. Therefore, consumers and other users of triclosan products suffer, at a minimum, economic detriment from having purchased a product that fails to perform as indicated, and, at maximum, potential danger to their health and safety.

#### *Relevant Corporate Decisions about Triclosan*

This Amended Petition explains the current scientific data and evidence demonstrating triclosan's inadequacies and dangers. In addition to addressing certain studies and reports, the Amended Petition also discusses notable corporate and governmental decisions that attest to the growing awareness of these problems. For example, 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.<sup>5</sup> This request seeks to cancel the use of Ciba triclosan "as an antimicrobial for the protection of polymers/plastics and textiles."<sup>6</sup>

Thus 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,

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<sup>5</sup>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.

<sup>6</sup> Ciba website, available at <http://www.ciba.com/ind-pc-triclosan-prod-safe.htm>.

which [it claims] are supported by an exhaustive database of safety research, from the proliferation of triclosan made by other manufacturers.”<sup>7</sup> It is fair to question 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 change<sup>8</sup> must be seen in light of the growing scientific consensus and public concern about triclosan usage. Additionally, and necessarily, the decision stands as a serious indictment against those “other manufacturers” to which Ciba refers.

#### *Relevant Decisions of Other Governments about Triclosan*

Perhaps Ciba’s decision reflects the influence of a recent opinion, adopted just two months earlier, by the European Commission’s Scientific Committee on Consumer Products<sup>9</sup>(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

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<sup>7</sup> *Id.* (Emphasis added)

<sup>8</sup> 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.

<sup>9</sup> European Commission, Health & Consumer Protection Directorate-General, Scientific Committee on consumer Products, *Opinion on Triclosan*, COLIPA No. P32, SCCP/1192/08, adopted at 19<sup>th</sup> plenary of 21 January 2009.

exposure.”<sup>10</sup> 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.”<sup>11</sup>

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 severe qualification to this determination:

Importantly, before a final conclusion on the safety of triclosan in cosmetic products can be reached, the potential development of resistance to triclosan and cross-resistance by certain micro-organisms must be assessed. This aspect is not covered in this document....<sup>12</sup>

On the question of bacterial resistance and cross-resistance by virtue of triclosan usage, this Amended Petition cites and discusses the substantial and compelling evidence confirming the existence of those phenomena.

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

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<sup>10</sup> *Id.* at p. 123.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.* Also, the SCCP Opinion did not assess inhalation exposure to triclosan from spray products (e.g. deodorants). *Id.*

accepting triclosan” for inclusion in the process potentially leading to a listing,<sup>13</sup> OEHHA nonetheless included triclosan in its prioritization groupings.<sup>14</sup>

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.

#### *Relevant EPA Decisions about Triclosan*

Petitioners also note, on the other hand, that on September 18, 2008, EPA determined that triclosan was eligible for “reregistration” as a pesticide under the Federal Insecticide, Fungicide and Rodenticide Act<sup>15</sup> (FIFRA). In response to the EPA Reregistration Eligibility Decision<sup>16</sup> (RED), and as provided for in the decision, Petitioners submitted their *Comments on EPA/OPP Reregistration Eligibility Decision for Triclosan* to EPA<sup>17</sup> (EPA/ RED Comments). In those EPA/RED Comments, Petitioners strongly opposed the EPA decision and discussed the substantial base of scientific evidence supporting their position. Petitioners’ opposing points in response to the RED will be presented at appropriate points in this Amended Petition.

Petitioners, therefore, take the position that the EPA RED, depending on the topic addressed, contained incomplete data, inadequate analysis, or both. Even EPA itself

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<sup>13</sup> See, Letter from Lisa Navarro, of Ciba, to OEHHA, May 4, 2009, available at [http://www.oehha.ca.gov/prop65/public\\_meetings/052909coms/triclosan/CibaCorpTriclosan.pdf](http://www.oehha.ca.gov/prop65/public_meetings/052909coms/triclosan/CibaCorpTriclosan.pdf).

<sup>14</sup> 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](http://www.oehha.ca.gov/prop65/public_meetings/cic060509.html).

<sup>15</sup> 7 U.S.C. §§136-136y.

<sup>16</sup> See, *Reregistration Eligibility Decision for Triclosan*, September 18, 2008, **Document ID:** EPA-HQ-OPP-2007-0513-0033, available at <http://www.regulations.gov>. See also, *Triclosan; Reregistration Eligibility Decision; Notice of Availability*, Federal Register: October 29, 2008, Vol. 73, No. 210, pp. 64331-64333.

<sup>17</sup> *Comments on EPA/OPP Reregistration Eligibility Decision for Triclosan* to EPA, (EPA/Red Comments), EPA Docket No.: EPA-HQ-OPP-2007-0513, available at <http://www.regulations.gov>.

seemed to cast a tone of uncertainty in and around 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.<sup>18</sup> Accordingly, we urge that FDA, to the extent it takes into account the EPA RED, consider carefully our points made herein in opposition to the EPA RED.

Moreover, we observe that it is well-supported in the law that an agency must make its own complete and independent decision in cases presented to it for decision. The EPA RED decision cannot constrain, and certainly does not excuse, FDA from fulfilling its mandated duties under the FFDCA. The United States Supreme Court made this latter point forcefully in *Massachusetts v. Environmental Protection Agency*.<sup>19</sup> Responding to EPA’s claim that it could not regulate greenhouse gas emissions because to do so would interfere with the U. S. Department of Transportation’s statutory mandate to regulate mileage standards, the Court rejected the argument:

[T]hat DOT sets mileage standards in no way licenses EPA to shirk its environmental responsibilities. EPA has been charged with protecting the public's "health" and "welfare," . . . a statutory obligation wholly independent of DOT's mandate to promote energy efficiency . . . The two obligations may overlap, but there is no reason to think the two agencies cannot both administer their obligations and yet avoid inconsistency.<sup>20</sup>

Finally, Petitioners’ EPA Comments addressed EPA’s complete rejection of the “precautionary principle.” Petitioners strongly urge FDA to evaluate this Amended

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<sup>18</sup> EPA RED, p. 41.

<sup>19</sup> *Massachusetts v. Environmental Protection Agency*, 549 U.S. 497 (2007)

<sup>20</sup> 549 U.S. 531-32.

Petition in the context of this powerful concept; it is fundamental to any truly competent and dedicated system of health and environmental protection. This was the approach of the British Royal Commission on Environmental Pollution in its 2003 recommendation for a regulatory ban on synthetic chemicals:

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.<sup>21</sup>

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."<sup>22</sup>

#### *Relevant FDA Decisions about Triclosan*

Unfortunately, one of the most prominent and consequential failures to observe the precautionary principle today is codified in a part of the FDA drug regulatory system that regulates many triclosan products. This is the system for "Over-the-Counter" (OTC) drug regulation through the development of a tentative, and then a final, "monograph." Essentially, under this system, manufacturers are generally allowed to manufacture and market drug products *unless* they are determined in a final rule to be unsafe or ineffective. The problem is that such a determination comes *at the conclusion of an*

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<sup>21</sup> Royal Commission on Environmental Pollution, Twenty-fourth Report, *Chemicals in Products: Safeguarding the Environment and Human Health*, June 3, 2003.

<sup>22</sup> 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](http://www.panap.net/uploads/media/PAN_precaution_14_Sep_06.pdf) (PAN Paper).

*exceedingly lengthy regulatory process.*<sup>23</sup> As a result, triclosan products—with their ever-expanding volume and variety of uses—have continued to impose exceedingly large and dangerous burdens on the human body and to pose significant threats to larger ecosystems in the environment.

Antiseptics regulated as drugs by FDA come under either the monograph or the “new drug application” (NDA) OTC processes, and a majority of these antiseptics (including triclosan) are regulated under the monograph system. FDA first proposed rulemaking to establish a monograph for OTC topical antimicrobial drug products in 1974. Even at that early point, experts on the Advisory Review Panel raised certain points that should have elicited precautionary action. The Panel (1) noted the potentially widespread use of antimicrobial soaps; (2) observed that these products might well enjoy lifetime use by humans; (3) identified their “hypothetical” concern that routine use of topical antimicrobials may have a long-term harmful effect; (4) noted the insufficiency of existing studies to demonstrate the ability of those soaps to prevent skin infection; and (5) did not recommend any active ingredients in these products as generally recognized as safe and effective.<sup>24</sup>

In January, 1978, FDA published a rulemaking proposal as a “Tentative Final Monograph” (TFM) for OTC topical antimicrobial drug products.<sup>25</sup> Over the years thereafter, FDA continually reopened the administrative record, effectively allowing the continued marketing and use of triclosan. Then, in 1994, FDA issued a “reproposal [of

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<sup>23</sup> See, Memorandum from Topical Antiseptic Review Team to members of the Nonprescription Drugs Advisory Committee (NDAC), consultants and guests, September 22, 2005, in preparation for an October 20, 2005 NDAC meeting (NDAC Memo), available at [http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4184B1\\_01\\_01-FDA-Executive%20Summary.pdf](http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4184B1_01_01-FDA-Executive%20Summary.pdf).

<sup>24</sup> See, *Establishment of a Monograph for OTC Topical Antiseptic Drug Products*, 39 Fed. Reg. 33102 (Sept. 13, 1974); NDAC Memo at 4.

<sup>25</sup> *Tentative Final Monograph for OTC Topical Antimicrobial Drug Products*, 43 Fed. Reg. 1210 (Jan. 6, 1978).

the prior TFM] regarding health-care antiseptic drug products.”<sup>26</sup> Of course, because the rulemaking was not one for a “final” monograph, triclosan marketing and use continued, expanding vastly in both the volume and variety of triclosan product consumption.

The 1994 TFM is 15 years old. Further, and as a consequence, many of the scientific studies offered in the comments and considered by FDA date in the 1970s and the early 1980s.<sup>27</sup> The rapid march of modern scientific research and discovery since then provides stark and telling commentary about certain conclusions made in that document.

For example, FDA concludes in the 1994 TFM that “there is no proliferation problem with triclosan,”<sup>28</sup> a reversal of its conclusion in the prior 1978 TFM.<sup>29</sup> This conclusion was critical, as the problem of pervasive use, including cumulative impact, and the resultant impact on body burden had been a serious concern from the earliest regulatory deliberations. One commentator, “the manufacturer of triclosan,” denied that proliferation was occurring and even claimed that sales diminished during 1973-77 for certain products. It even offered that if FDA would place triclosan in “Category I” (safe and effective and not misbranded) for use in antimicrobial soaps, “it would limit sales of triclosan to OTC use in antimicrobial and deodorant soaps, underarm deodorants, and registered [EPA] ... pesticide products.”<sup>30</sup> Obviously, today, FDA’s conclusion is flatly unsupported.<sup>31</sup> It is notable, in this regard, that Ciba’s recent decision to cancel certain

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<sup>26</sup> *Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products*, 59 Fed. Reg. 31402, 31403 (June 17, 1994). FDA published a separate TFM for “first aid” products (e.g., skin antiseptics, skin wound cleansers and skin wound protectants) in 1991, at 56 Fed. Reg. 33644. The 1994 TFM applies only to non-first aid topical antimicrobials, or “health-care antiseptics.”

<sup>27</sup> See, the 1994 discussion specifically addressing triclosan, at 59 Fed. Reg. 31426-31428.

<sup>28</sup> 59 Fed. Reg. 31428.

<sup>29</sup> 43 Fed. Reg. 1210, at 1231 and 1233.

<sup>30</sup> 59 Fed. Reg. 31426-31427.

<sup>31</sup> See, EPA RED, pp. 9, 49-60 (Appendix A, Use Patterns Eligible for Reregistration).

EPA registrations was made because of “the proliferation of triclosan made by other manufacturers.”<sup>32</sup>

Even with certain key mistaken assumptions, however, the 1994 TFM still concluded that “with regard to safety for use as an antiseptic handwash or health-care personnel handwash and surgical hand scrub, triclosan remains classified in Category III for safety for long-term use.”<sup>33</sup> The agency also reclassified triclosan, at certain concentrations, “from Category II to Category III for effectiveness...[noting that ] additional studies are needed before triclosan can generally be recognized as effective for specific” health care professional and first aid uses.<sup>34</sup> Under applicable regulations, a Category III classification means that available data are insufficient to classify a drug as either a Category I drug (“generally recognized as safe and effective and not misbranded”) or a Category II drug (“not being generally recognized as safe and effective or would result in misbranding.”)<sup>35</sup>

Thus, although the 1994 TFM had significant limitations, it actually contained sufficient information that should have sounded a note of alarm leading to precautionary action. That document is, nonetheless, both inadequate and outdated. Therefore, both FDA’s specific analysis of triclosan and the monograph method of regulating OTC drug use give rise to legitimate concern and criticism.

## II. Action Requested

This Amended Petition seeks a ban on widespread use of triclosan products and applications as registered by the FDA. Petitioners are not seeking a ban on triclosan uses

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<sup>32</sup> *Id.* (Emphasis added)

<sup>33</sup> 59 Fed. Reg. 31427.

<sup>34</sup> *Id.*

<sup>35</sup> 21 C.F.R. §330.10(a)(6)(i),(ii).

in controlled settings by medical and health professionals, such as in hospitals, medical care facilities and laboratories.

### III. Statement of Grounds

Triclosan is a “cosmetic”<sup>36</sup> and a “drug”<sup>37</sup> for purposes of the FFDCA, and as such, its usage, as approved by the FDA, constitutes an “adulterated” and “misbranded” cosmetic and drug in violation of that Act.<sup>38</sup>

#### A. The Presence of Triclosan in the Human Body Imposes an Immense and Dangerous “Body Burden.”

Because of its widespread usage and its properties, triclosan can be found in blood,<sup>39</sup> urine,<sup>40</sup> and breast milk<sup>41</sup> 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.<sup>42</sup> Indeed, one study, conducted by scientists at the Center for Disease Control and Prevention, (CDC) took particular note that the “high frequency of detection [in a study of 2.517 urine samples using the NHANES method] is most likely with daily use by the

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<sup>36</sup> See, FFDCA §210(i), 21 U.S.C. §321(i), defining the term “cosmetic” as including “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance.” The definition also includes components of any such articles, but it does not include soap.

<sup>37</sup> See, FFDCA § 201(g)(1), 21 U.S.C. §321(g)(1), defining the term “drug” as an article, or component of an article that is: recognized in one of the official “compendia”<sup>37</sup>; “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;” or “intended to affect the structure or any function of the body of man or other animals.”

<sup>38</sup> See FFDCA § 501, 21 U.S.C. § 351 (adulteration of drugs); FFDCA § 502 , 21 U.S.C. § 352 (misbranding of drugs); FFDCA § 601, 21 U.S.C. §361 (adulteration of cosmetics); FFDCA § 602, 21 U.S.C. § 362 (misbranding of cosmetics).

<sup>39</sup> 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).

<sup>40</sup> 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).

<sup>41</sup> 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).

<sup>42</sup> 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).

U.S. general population of [triclosan-containing] consumer products.”<sup>43</sup> As described throughout this Amended Petition, given the dangers of each individual source of triclosan, the cumulative effect from all sources of this lipophilic (bioaccumulative in fatty tissues) substance 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)<sup>44</sup> 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.<sup>45</sup> Urine is not the appropriate fluid to *quantitatively* assess triclosan exposure, though it does provide useful *qualitative* information on population exposure to triclosan.

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<sup>43</sup> 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).

<sup>44</sup> NHANES data for triclosan can be found at <http://www.cdc.gov/nchs/nhanes.htm>.

<sup>45</sup> 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*<sup>46</sup> (Dietary Risk Assessment) concluded that “[n]one of the indirect food contact scenarios appear to exceed [the] Agency’s level of concern.”<sup>47</sup>
  - 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).”<sup>48</sup>
  - Yet, EPA admits that “no residue chemistry data based on [agency guidelines] were submitted nor was it requested.”<sup>49</sup>

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<sup>46</sup> EPA’s *Dietary Risk Assessment for Triclosan for the RED Process, August 11, 2008*(Dietary Risk Assessment).

<sup>47</sup> Dietary Risk Assessment. (unpaginated)

<sup>48</sup> EPA RED, p. 15.

<sup>49</sup> 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.<sup>50</sup> 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.

B. Bacterial Resistance to Antibiotic Medications and Antibacterial Cleansers  
Emanates from the Growing Body Burden of Triclosan

“The major driving force for development of resistance in bacteria to antimicrobial agents ... is the use of antimicrobials themselves.”<sup>51</sup> 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 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

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<sup>50</sup> Sandborgh-Englund et al. 2006. Pharmacokinetics of triclosan following oral ingestion in humans. *J. Tox. and Environ. Health. Part A* 69:1861-1873

<sup>51</sup> 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.

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. To achieve 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 time, temperature and amount of the substance needed in the study far exceeded that for the average hand washing.<sup>52</sup>

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.”<sup>53</sup>

The problem, therefore, is the widespread use of triclosan. And this should be distinguished from the more restricted, knowledgeable and careful use of it by medical

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<sup>52</sup> Steward B. Levy, *Antibacterial Household Products: Cause for Concern*, Conference Presentation, *Emerging Infectious Diseases*, Vol. 7, No. 3 Supplement, June 2001, at 513.

<sup>53</sup> *Triclosan and Antimicrobial Resistance in Bacteria: An Overview*, at 88.

professionals.<sup>54</sup> 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.”<sup>55</sup>

Triclosan’s broad-spectrum antibacterial properties have 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.<sup>56</sup>

While ordinary, healthy adults are 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.<sup>57</sup> Patients returning home who continue to take antibiotics enter an environment rife with antimicrobial and other products containing

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<sup>54</sup> 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.

<sup>55</sup> *Antibacterial Household Products: Cause for Concern*, at 512.

<sup>56</sup> Stuart B. Levy, *Antibiotic and Antiseptic Resistance: Impact on Public Health*, *Pediatric Infectious Disease Journal*, Vol. 19, No. 10, Oct. 2000, at S121.

<sup>57</sup> *Id.*

triclosan. Hence, the danger of the antibiotics being rendered ineffective could be dangerously high.<sup>58</sup>

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."<sup>59</sup> But to the contrary, as discussed above, several peer-reviewed studies highlighting the concerns many 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,"<sup>60</sup> 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 Resistance<sup>61</sup> (Task Force). EPA even admits that "none of the goals [of the Task Force] are associated with a specific active ingredient."<sup>62</sup>

C. Endocrine Disruption is a Potential Result of Triclosan Bioaccumulation in the Body

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

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<sup>58</sup> *Id.*

<sup>59</sup> EPA RED, p. 40.

<sup>60</sup> EPA RED, p. 40.

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

“further investigation is needed on the effects of triclosan on the thyroid”<sup>63</sup> 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 androgen and estrogen receptors.”<sup>64</sup> As the discussion below demonstrates, there exists considerable evidence of these effects. 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.<sup>65</sup> Further, EPA was recently advised by the National Research Council to consider the cumulative effects of chemicals with similar toxicological outcomes, including neurodevelopmental toxins.<sup>66</sup>

Finally, in refusing 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 Program<sup>67</sup> (EDSP). Yet, establishment of the EDSP has not been completed, and thus the RED

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<sup>63</sup> EPA RED, p. 13.

<sup>64</sup> EPA RED, p. 35.

<sup>65</sup> 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.

<sup>66</sup> 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](http://www.nap.edu/catalog.php?record_id=12528)

<sup>67</sup> FFDCA §408(p)(1), 7 U.S.C. §346a(p)(1).

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 amphibians and fish.<sup>68</sup> 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.”<sup>69</sup>

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.<sup>70</sup>

The protocol for the study employed the Endocrine Disruptor Screening Program (EDSP) male pubertal protocol, administering triclosan daily by oral gavage until

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<sup>68</sup>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).  
; 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).

<sup>69</sup> 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).

<sup>70</sup> 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).

necropsy.<sup>71</sup> 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 potential concern for 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.<sup>72</sup>

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 T<sub>4</sub> [thyroxine] in rats.”<sup>73</sup> 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.<sup>74</sup>

### *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

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<sup>71</sup> *Id.* at 57.

<sup>72</sup> *Id.* at 61-62.

<sup>73</sup> 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).

<sup>74</sup> *Id.* at 196.

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.”<sup>75</sup>

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 oestrogen.”<sup>76</sup> 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.<sup>77</sup> Triclosan has been thought to be one of the substances in cosmetics that alter cell DNA and interfere with normal growth regulatory pathways (including oestrogen action).<sup>78</sup>

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

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<sup>75</sup> 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).

<sup>76</sup> *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).

<sup>77</sup> Darbre, *Environmental Oestrogens, Cosmetics, and Breast Cancer*, at 127.

<sup>78</sup> 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).

Numerous studies attest to the problems triclosan can cause for the skin. Reports observe such problems as dermatitis, or skin irritation,<sup>79</sup> photoallergic contact dermatitis,<sup>80</sup> eczematous rash, and even immunotoxic and neurotoxic reactions to the substance.<sup>81</sup>

#### E. Babies and Other Children are Especially Vulnerable to Triclosan

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 also more permeable than an adult's,<sup>82</sup> 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.<sup>83</sup> 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

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<sup>79</sup> 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).

<sup>80</sup> 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).

<sup>81</sup> Stafford, J., *Germ Warfare*, *Voices, Health and Fiction*, C2-C3 (May 5, 1997).

<sup>82</sup> Silver, L. 2007. Baby Care Products. Prevention and Practice. *Learning and Developmental Disabilities Initiative*. Institute for Children's Environmental Health (ICEH).

<sup>83</sup> 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>.

exposure can adversely affect a child's neurological, respiratory, immune, and endocrine system, even at low levels.<sup>84</sup>

#### F. Triclosan is Present Abundantly and Pervasively in Wastewater and this Poses Significant Risks for Human Health and the Environment

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.<sup>85</sup> The sewage sludge is spread on land, and triclosan leaches down through the soil and runs off into surface water from the fields.<sup>86</sup> 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

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<sup>84</sup> 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](http://www.net.org/health/tri_report.pdf) (accessed 6/2/05).

<sup>85</sup> Heidler, J and RU Halden, *Mass Balance Assessment of Triclosan Removal During Conventional Sewage Treatment*, *Chemosphere* 66: 362-69, (2007)

<sup>86</sup> 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.

of time.<sup>87</sup> 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.<sup>88</sup> Wastewater, in fact, is “the principal pathway of [triclosan] contamination” in estuarine sediments.<sup>89</sup> 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.”<sup>90</sup> 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 wastewater treatment.”<sup>91</sup> 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:

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<sup>87</sup> 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).

<sup>88</sup> See, Technical Report, Table 12, p 41..

<sup>89</sup> 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.

<sup>90</sup> EPA RED, p. 28.

<sup>91</sup> *Id.* at 29.

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.<sup>92</sup>

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.<sup>93</sup> 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.<sup>94</sup>

In other areas, EPA admitted to considerable uncertainty about ecological exposure and risk.<sup>95</sup> 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.

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

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<sup>92</sup> Id. at

<sup>93</sup> *Data Requirements for Antimicrobial Pesticides*, 73 Fed. Reg. 59382 (Oct. 8, 2008).

<sup>94</sup> 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.

<sup>95</sup> EPA RED at 31-33.

streams across 30 states during 1999 and 2000.<sup>96</sup> 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.<sup>97</sup> 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.<sup>98</sup>

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."<sup>99</sup> Thus, not only is triclosan present in the environment initially, but it remains in the environment even after the wastewater treatment process.

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

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<sup>96</sup> 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).

<sup>97</sup> *Id.* at 1207 (Fig. 2), 1208.

<sup>98</sup> *Id.*

<sup>99</sup> Jochen Heidler, Rolf U. Halden, *Mass Balance Assessment of Triclosan Removal During Conventional Sewage Treatment*, Chemosphere 66, 362-369, at 368, (2007).

bioaccumulative.<sup>100</sup>) Generally, therefore, triclosan is present in a large number of waterways, and thus humans and animals are vulnerable to its effects. As described below, there are numerous potential adverse impacts.

G. Triclosan Usage Poses Health Risks Because it Forms Carcinogenic Dioxin and Chloroform Under Certain Conditions

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 triclosan,<sup>101</sup> during the manufacture of many products, and upon the incineration of triclosan.<sup>102</sup> 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 dioxin in the water. This suggests that sunlight could transform triclosan into dioxin naturally.<sup>103</sup> 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 danger is that exposure of sunlight to solid-state triclosan, such as on commercial textile products, causes formation of small amounts of dioxin.<sup>104</sup>

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<sup>100</sup> 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).

<sup>101</sup> Menoutis, J. and A.I. Parisi, *Triclosan and its impurities*, Triclosan Review Series, Quantex Laboratories, Inc., available at <http://www.quantexlabs.com/triclosan.htm>.

<sup>102</sup> 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).

<sup>103</sup> 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).

<sup>104</sup> 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).

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.<sup>105</sup> 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.<sup>106</sup> As chloroform has been classified as a probable human carcinogen,<sup>107</sup> serious concerns exist, not only about the use of dishwashing liquids but also about the use of toothpastes and handsoaps.

#### H. Triclosan is Highly Toxic to Various Forms of Algae and This Can Cause Both Specific and Systemic Ecological Damage

Triclosan can have detrimental effects on aquatic ecosystems. Triclosan has been found to be highly toxic to different types of algae.<sup>108</sup> Triclosan effluents affect both the structure and the function of algal communities in stream ecosystems.<sup>109</sup> Because algae are the first-step producers in aquatic ecosystems, high levels of triclosan discharged into

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<sup>105</sup> 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.

<sup>106</sup> *Ibid.*

<sup>107</sup> EPA, Office of Pesticide Programs, *List of Chemicals Evaluated for Carcinogenic Potential*, updated July 19, 2004.

<sup>108</sup> 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).

<sup>109</sup> 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).

the environment may cause widespread negative consequences, including “the possible destruction of the balance of the ecosystem.”<sup>110</sup> The risks are especially high immediately downstream from wastewater treatment plants.<sup>111</sup>

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.<sup>112</sup> 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.<sup>113</sup> Methyl triclosan, a transformation product of triclosan, has been found in fish.<sup>114</sup> 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.<sup>115</sup>

The EPA RED observed that in aquatic environments, “triclosan is expected to absorb to [sic] suspended solids and sediments and may bioaccumulate ... posing a concern for aquatic organisms.”<sup>116</sup> In fact, its own qualitative environmental risk assessment determined that levels of concern “were exceeded for aquatic plants.”<sup>117</sup> But,

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<sup>110</sup> 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).

<sup>111</sup> 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).

<sup>112</sup> 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).

<sup>113</sup> *Ibid.*

<sup>114</sup> 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).

<sup>115</sup> Ishibashi, H., N. Matsumura, M. Hirano, M. Matsuoka, et al., *Effects of Triclosan on the Early Life Stages and Reproduction of Medaka *Oryzias Latipes* and Induction of Hepatic Vitellogenin*, *Aquatic Toxicology* 67, 167-79 (2004).

<sup>116</sup> RED, p. 28-29.

<sup>117</sup> RED, p. 31.

as noted in this Amended 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.<sup>118</sup>

#### I. Triclosan Products Fail to Provide Many of its Claimed Benefits

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. As shown in the discussion below, numerous scientific studies seriously undercut and refute the main benefits that triclosan claims to confer.

As discussed in Section III (B) of this Amended 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.<sup>119</sup>

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<sup>118</sup> See, e.g., EPA RED, pp. 30-31.

<sup>119</sup> 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.”<sup>120</sup> 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.”<sup>121</sup> 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 encourage “continued research” on the use of common antimicrobials in consumer products and its impact on the *major health problem of antimicrobial resistance.*”<sup>122</sup>

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

## J. Conclusion

Petitioners have demonstrated in this Amended Petition that a substantial body of scientific studies, reports and other sources support our 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 FDA-approved

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<sup>120</sup> American Medical Association, 2000 Annual Meeting, *Reports of the Council on Scientific Affairs*, at 4 (2000).

<sup>121</sup> *Id.*

<sup>122</sup> *Ibid.*

applications is unsafe and ineffective, “adulterated,” “misbranded” and otherwise in violation of the FFDCA. In the interests of the protection of human health and the overall environment that supports it, Petitioners request that the FDA ban triclosan in accordance with the statement in Section II (Action Requested)

#### IV. Environmental Impact

FDA’s grant of this Amended Petition will not result in any adverse environmental impact. Further, Petitioners believe that action on this Amended Petition in the form of a ban on triclosan qualifies as a categorical exclusion under 21 CFR Part 25.<sup>123</sup>

#### V. Economic Impact

Extensive information on the economic impact of Petitioners’ request is required only when requested by the FDA.<sup>124</sup> Petitioners note generally that although the requested ban would impose economic impacts on producers and other businesses relative to the manufacture and sale of triclosan-related products, these costs would be overwhelmingly outweighed by several critical economic benefits: (1) the positive economic benefits of reduced healthcare costs associated with the reduced incidence of triclosan usage; (2) increased economic productivity in society due to a healthier population; and (3) reduced economic burdens on Publicly Owned Wastewater Treatment Works (POTWs) necessitated at present by the existence of triclosan in wastewater.<sup>125</sup>

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<sup>123</sup> 21 C.F.R. Part 25.

<sup>124</sup> 21 C.F.R. 10.30.10(b).

<sup>125</sup> For commentary on the special economic burden triclosan imposes in POTWs, see the Comments on EPA’s proposal on new data requirements for antimicrobial pesticides made by the National Association of

VI. Certification

The undersigned certifies that, to best of his knowledge and belief, this Amended Petition includes all information and views on which the Amended Petition relies, and that it includes representative data and information known to the Petitioners that are unfavorable to this Amended Petition.

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## Appendix A

### Organizations Supporting The Petition

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