Environmental Protection Agency
Office of Pesticide Programs

Comments on EPA/OPP Reregistration Eligibility Decision for Triclosan

By

Food and Water Watch and Beyond Pesticides

Introduction

Food and Water Watch, Beyond Pesticides and the attached list which includes an additional 35 organizations appreciate the opportunity to comment on the Environmental Protection Agency's (EPA) Final Reregistration Eligibility Decision (RED) for triclosan. We appreciate the agency's consideration of previous comments submitted on July 7, 2008.

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 U.S. Food and Drug Administration (FDA) and the EPA. For those products under EPA's jurisdiction, the agency has found that the currently registered uses of triclosan are eligible for reregistration., but eligibility excludes its use as a materials preservative in paint, which has been voluntarily cancelled by the registrant.

As set out in these Comments, we applaud certain decisions made by EPA in its risk assessment and decisionmaking process. At the same time, however, we wish to register our concerns about a number of areas in which the agency has proceeded improperly and inadequately, in violation of applicable laws and policies. Our interest is the same as that of the laws and policies that constrain and guide EPA's exercise of authority: the highest levels of protection for human health and the environment.

In addition to detailing specific inadequacies in the RED and its supporting assessments, these Comments also express our great concern with the overall governmental structure of, and approach to, triclosan regulation. That regulatory system is fractured, incomplete and uncoordinated. Thus, for example, the allocation of duties between EPA and FDA has left significant gaps in regulatory protection against credible environmental and health threats.

Further exacerbating the problem is a pervasive attitude--both *inter*-agency and *intra*-agency--that any problem apparently falling within the regulatory mandate or authority of another agency or office need not—indeed must not—be addressed. A central fallacy in this attitude is the failure to understand the simple but frequent reality that the release of a harmful substance into the environment may constitute a violation of *more than one* environmental statute. As we note at various points in these Comments, the fact that an approved use of triclosan violates another federal statute only *strengthens* the basis for concluding that it will cause "unreasonable adverse effects on the environment" under FIFRA. Rather than treating such an occurrence as an opportunity (or a mandate) to cease any further inquiry, affected agencies (or intra-offices) should work cooperatively in the interest of public health, safety and welfare. This notion goes to the heart of the objectives of environmental regulation, and this is why the Food Quality Protection Act incorporates concepts of "cumulative risk" and "aggregate exposure" assessment as a key requirement.

EPA's narrow, skeptical attitude about environmental protection has been criticized by the United States Supreme Court. In *Massachusetts v. Environmental Protection Agency*, the Court addressed 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:

> EPA finally argues that it cannot regulate carbon dioxide emissions from motor vehicles because doing so would require it to tighten mileage standards, a job (according to EPA) that Congress has assigned to DOT. . . But that 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.[1]

I. Applicable Laws and Policies

A. Federal Insecticide, Fungicide and Rodenticide Act

1. Reregistration of Registered Pesticides

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.[2] Triclosan was first registered by EPA in 1969. EPA is now in Phase V of that reregistration review, having completed the requirements of Phases I-IV for listings of active ingredients, submissions by registrants and independent initial review by the agency. EPA, in completion of its Phase V review for triclosan, has issued the present final RED.

2. Procedures and Standards for Reregistration

The 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

[1] 549 U.S. 497 (2007).
[2] 7 U.S.C. § 136a-1(a).

Amendments of 1988, the Food Quality Protection Act of 1996 and the Pesticide Registration Improvement Act of 2003, all evidence a growing concensus 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.[3]

Each Phase of the reregistration review process reflects an enhanced emphasis on human health and safety and protection of the environment. 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. Thus:

- Phase I, in requiring the listing of active ingredients of targeted pesticides, directs the EPA to "give priority" to pesticide active ingredients that (A) are used on or in food or will result in postharvest residues; (B) may result in residues of potential toxicological concern in potable ground water, edible fish or shellfish; (C) have previously been determined by EPA to have "significant outstanding data requirements;" or (D) are used on crops where worker exposure is most likely to occur.
- Phase II requires, among other things, submission by registrants of supporting data, Such data are "inadequate if the data are derived from a study with respect to which the registrant is unable to make the certification prescribed …[by law] that the

[3] 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."

registrant possesses or has access to raw data used in or generated by such study. There is a rebuttable presumption of inadequacy for studies submitted before January 1, 1970.

- Phase III requires registrants to submit summaries of previously submitted studies, both those considered to be adequate, and those that may not be but should be deemed to be, adequate under EPA requirements. Registrants must reformat this data to show clearly information concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, teratogenicity and residue chemistry of pesticide active ingredients submitted before January 1, 1982. Phase III requires submission of new information required by EPA, with identification of adverse effects.
- Phase IV provides for an independent review and identification of outstanding data requirements by EPA. EPA must determine any outstanding data requirements and publish a notice of such inadequacies. Phase IV requirements reflect the seriousness and the centrality of complete, accurate and updated data in the registration process.
- Phase V culminates the reregistration process. It requires EPA to conduct a thorough, comprehensive examination of all data submitted in support of pesticide re-registration. Based on this review, the Agency will either re-register a pesticide or take

other appropriate regulatory action. Also, where EPA has sufficient information with respect to dietary risk of an active ingredient, it must "reassess each associated tolerance and exemption from the requirement for a tolerance" issued under the Federal Food, Drug and Cosmetic Act. Where the information supplied warrants it, EPA must also "determine whether additional tolerances or exemptions should be issued."[4]

Upon completion of these five phases, EPA must determine whether the pesticide meets the requirement for initial registration under FIFRA Section 3(c)(5):

- Its composition is such as to warrant the proposed claims for it;
- Its labeling and other material required to be submitted comply with the requirements set out in 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."[5]

As these Comments explain throughout, EPA conducted its reassessment of triclosan inadequately and improperly. This failure violated express requirements of FIFRA and would allow widespread use of a substance that is a demonstrated threat to human health and safety and the environment.

[4] 7 U.S.C. § 136a-1 (b)-g).
[5] 7 U.S.C. § 136a (c).

B. Federal Food, Drug and Cosmetic Act

The Federal Food, Drug and Cosmetic Act (FFDCA) was first enacted by Congress in 1938 to provide requisite authority and impose certain mandates for the Food and Drug Administration (FDA) to oversee the safety of food, drugs, and cosmetics.[6] FFDCA Section 408 authorizes EPA to set tolerances, or maximum residue limits, for pesticide residues on foods. The FFDCA 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." To make the safety finding, EPA considers, among other things: the toxicity of the pesticide and its break-down products, aggregate exposure to the pesticide in foods and from other sources of exposure, and any special risks posed to infants and children.[7]

We believe EPA, in its reregistration decision, has violated the FFDCA.

C. Clean Water Act

The Clean Water Act[8] (CWA) is the basic structure for regulating discharges of pollutants into the waters of the United States and regulating quality standards for surface waters. Under the CWA, EPA has implemented pollution control programs such as setting wastewater standards for industry and water quality standards for all contaminants in surface waters.

[6] 21 U.S.C. §301 et seq.
[7] 21 U.S.C. § 346a (a)-(c).
[8] 33 U.S.C. §1251 et seq.

As described in these Comments, EPA's failure to conduct a proper reregistration process for triclosan as required under FIFRA will have the follow-on effect of allowing the discharge of a harmful pollutant into "the waters of the United States" and permitting the contamination of surface waters. In effect, EPA's failure to implement properly one federal environmental statute (FIFRA) directly enables a violation of another federal environmental statute (CWA).

D. Safe Drinking Water Act

The Safe Drinking Water Act[9] (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.

As explained below, EPA's reregistration decision would allow for a violation of SDWA, in that triclosan would be allowed to contaminate drinking water at levels that threaten human health and the environment.

[9] 42 U.S.C. § 300f-300j-26.

D. Endangered Species Act

The Endangered Species Act[10] (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.

As described in these Comments, EPA's failure to conduct a proper reregistration of triclosan as required under FIFRA will result in a federal agency authorization that will jeopardize the continued existence of listed threatened and endangered species and may destroy or adversely modify designated critical habitats. Again, as with CWA, EPA's failure to implement properly one federal environmental statute (FIFRA) will directly enable violation of another federal environmental statute (ESA).

E. Precautionary Principle

"Essentially the precautionary principle directs that action be taken to reduce risk from chemicals in the face of uncertain but suggestive evidence of harm."[11] To this end, the British Royal Commission on Environmental Pollution made the following recommendation in 2003:

> 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

[10] 7 U.S.C. §136; 16 U.S.C. §460 et seq.

[11] 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)

from the market immediately.[12]

As we explain more fully below, the threats to human health and the environment posed by triclosan, particularly as it affects endocrine disruption and antibacterial resistance, have been sufficiently and credibly raised so as to make precautionary action by the agency imperative. Therefore, it was improper as a matter of law and policy for the agency to decline to carry out thorough risk assessments in these areas of exposure.

II. EPA's Reconsideration of Certain Omissions and Inadequacies in the Preliminary Risk Assessment Was Proper

EPA properly included the final RED certain types of triclosan exposure risks that had been omitted in the preliminary RED. We applaud the inclusion of these exposures, and we offer in certain instances comments about how the assessment can be improved:

- **Separate Analysis for Children Under Six Years Old.** It is imperative that assessments of exposures for this sensitive group be conducted, especially considering the numerous routes of exposure that include nursing, object-to-mouth, hand-to-mouth and dust inhalation. Further, as EPA noted in the RED, "NHANES data do not take into account the potential exposure pathways of triclosan-treated products for younger children." RED, pp. 17-18, 20 22-23.
- **Dermal and Inhalation Assessments.** These areas are important and were properly included. RED, pp. 13-19.

[12] Royal Commission on Environmental Pollution, Twenty-fourth Report,, *Chemicals in Products: Safeguarding the Environment and Human Health*, June 3, 2003. See also, PAN Paper, p. 1; Wingspread Conference on the Precautionary Principle, January 28, 1998, available at http://www.sehn.org/wing.html.

- **Expanded Efforts and More Monitoring Requests**. More effort is being put into evaluating triclosan in environmental compartments, with requests for monitoring data from registrants. This includes EPA's monitoring requirement relative to effluents from triclosan-producing facilities. We note here the potential nexus between potential FIFRA and CWA impacts and the importance of coordinated action between EPA offices. RED, p. 20-23, 38-39.
- **Accelerated Registration Review.** We also support the agency's decision to accelerate the schedule for the registration review process for triclosan, in light of ongoing research and the emerging scientific database for triclosan. However, we are concerned about immediate harm associated with triclosan use under the RED, given that, as indicated in these Comments, the process provides inadequate protection of public health and the environment.

The aforementioned areas of improvement in the triclosan reregistration process are to be applauded. At the same time, we would also like to address certain remaining areas in the RED that we find to be deficient. They are described and discussed below.

III. EPA's Risk Assessment is Deficient and Therefore the Agency's Reregistration Decision is Incorrect

A. EPA's Toxicity Analysis is Inadequate

Based on its evaluation of information in *5-Chloro-2-(2,4-dichlorophenoxy)phenol (Triclosan): Risk Assessment for the Reregistration Eligibility*

Decision (RED) Document [13] (Risk Assessment) and in *5-Chloro-2-(2,4-dichlorophenoxy)phenol (Triclosan): Toxicology Chapter for the Reregistration Eligibility Decision Document,*[14] (Toxicology Chapter) EPA determined that the toxicological database for triclosan "is adequate to support a registration eligibility decision."[15] Yet this decision is flawed, as the database supporting the decision is insufficient as a basis for the decision.

1. Endocrine Disruption is a Valid Endpoint for Triclosan Assessment

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 thryroid homeostasis in the rat. EPA determined, however, that "further investigation is needed on the effects of triclosan on the thyroid"[16] 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."[17] In fact, there exists considerable evidence of these effects.

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.[18] Long term effects on fertility and metabolism were not

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[13] *5-Chloro-2-(2,4-dichlorophenoxy)phenol (Triclosan): Risk Assessment for the Reregistration Eligibility Decision (RED) Document* (Risk Assessment), September 15, 2008.
[14] *5-Chloro-2-(2,4-dichlorophenoxy)phenol (Triclosan): Toxicology Chapter for the Reregistration Eligibility Decision Document. (Toxicology Chapter)* [date]
[15] RED, p. 12.
[16] RED, p. 13.
[17] RED, p. 35.
[18] 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*

investigated but interference with these hormones during critical periods of development has the potential to cause long term and irreversible damage. The mode of action is hypothesized to be through binding the pregnane X receptor, causing an induction of steroid metabolizing enzymes in the liver potentially accelerating clearance of thyroid hormone.[19] This suggests that there is potential for additivity or synergism with other thyroid disruptors acting through a similar mode of action (e.g., PBDEs and PCBs).[20] When considering the toxicity of hormone disrupting chemicals, EPA was recently advised by the National Research Council to consider the cumulative effects of chemicals with similar toxicological outcomes, including neurodevelopmental toxins.[21] Before allowing the continued use of triclosan, EPA should consider the potential of this chemical to interact with other thyroid disrupting chemicals by doing a cumulative risk assessment.

In addition to the research conducted by EPA's own Office of Research and Development, numerous peer-reviewed scientific studies have implicated triclosan as an endocrine disruptor. For example, a study by Veldhoen, Skirrow and Osachoff concluded that triclosan, because it is structurally similar to thyroid hormone, may disrupt the normal growth and development mediated by thyroid hormone in wildlife and

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triclosan on puberty and thyroid hormones in male Wistar rats. Toxicol Sci. 2009 Jan;107(1):56-64. Epub 2008 Oct

21.

[19] Jacobs, MN, Nolan, GT, Hood, SR, Lignans, *Bacteriocides and organochlorine compounds activate the human pregnane X receptor (PXR)*. Toxicol Appl Pharmacol. 2005 Dec 1;209(2):123-33.

[20] Pacyniak EK, Cheng X, Cunningham ML, Crofton K, Klaassen CD, Guo GL. *The flame retardants, polybrominated diphenyl ethers, are pregnane X receptor activators.* Toxicol Sci. 2007 May;97(1):94-102.

[21] 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**

humans.[22] Also, a study by Foran, Bennett and Benson, demonstrated that triclosan possesses the capacity to act as an endocrine disruptor in Japanese medaka fry, as it is similar in character to non-steroidal estrogens.[23] A study by Gee, Taylor and Darbre explored the *in vitro* endocrine disrupting properties of triclosan and found that it possesses both oestrogenic and androgenic properties at environmentally relevant concentrations. The study advances the credibility of theses that the "endocrine activity of triclosan at low concentrations together with other [of its] adverse cellular actions …brings into question whether triclosan might contribute to the development of cancer."[24]

EPA expressly declined to consider the endocrine disrupting effects of triclosan, and this was a violation of law. It is legally insufficient for EPA to decline to make such an assessment merely because its Endocrine Disruptor Screening Program (EDSP) has not been completed. FFDCA Section 408(p), as amended by the FQPA, provides as follows:

> Not later than 2 years after August 3, 1996, the Administrator shall in consultation with the Secretary of Health and Human Services develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.[25]

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[22] Veldhoen, N., R.C. Skirrow, H Osachoff, et al, 2006, *The bactericidel agent triclosan modulates thyroid hormone-associated gene expression and disrupts postembryonic anuran development*, Acquatic Toxicology 80:217-227.

[23] Foran, C.M., E.R. Bennett, and W.H. Benson, *Developmental evaluation of a potential non-steroidal estrogen: triclosan.* Marine Environmental Research, 2000. 50(1-5): p. 153-156.

[24] Gee, R.H., et al., Oestrogenic and androgenic activity of triclosan in breast cancer cells. Journal of Applied Toxicology, 2008. 28(1): p. 78-91. See also, Darbre, P.D., Environmental oestrogens, cosmetics and breast cancer. Best Practice & Research Clinical Endocrinology & Metabolism, 2006. 20(1): p. 121-143.

[25] FFDCA §408(p)(1), 7 U.S.C. §346a(p)(1).

The section further requires that EPA implement the EDSP "[n]ot later than 3 years after August 3, 1996." The agency must also "provide for the testing of all pesticide chemicals …and …any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if …[EPA] determines that a substantial population may be exposed to such substance."[26] (Emphasis added) Further, EPA "shall issue an order" to pertinent registrants requiring testing and submission of relevant information, and the agency must issue a notice of intent to suspend the sale or distribution of the substance for failure of a registrant to comply with the order.[27] (Emphasis added) Despite the specific legislative mandate, the EDSP has not been implemented to the point of being a functional means of assessment, and, in any event, triclosan has not been listed on the "Draft List of Chemicals for Initial Screening." [28] Delay and other concerns have made the EDSP the focus of severe criticism.[29]

EPA essentially relies on the fact that the EDSP is still in its initial formative stages as a reason for not assessing triclosan's endocrine disruptive properties. But EPA cannot rely on the fact that the EDSP program has not developed a final list of potential endocrine disruptors (the initial list does not include triclosan) as a basis for avoiding performance of an assessment. Indeed, EPA has already set a precedent in its assessment of the substance atrazine for its potential endocrine disruptive effect on amphibians. EPA prepared an analysis in support of an Interim Reregistration Eligibility Decision on

[26] FFDCA §408(p)(2), (3), 7 U.S.C. §346(p)(2),(3).
[27] FFDCA §408(p)(5)(A), (C), 7 U.S.C. §346(p)(5)(A), (C).
[28] See, the EDSP webpage, at http://www.epa.gov/endo/.

[29] See, "Scientists criticize EPA chemicals screening program," The Dallas Morning News, May 27, 2007, available at http://www.dallasnews.com. ("Scientists say the Bush administration is developing a chemical testing program that favors the chemical industry when it comes to judging whether certain substances in the environment might cause cancer, infertility, or harm to babies in the womb.")

Atrazine, as explained in a document entitled *White Paper on Potential Developmental Effects of Atrazine on Amphibians.*[30] EPA evaluated the endocrine disruptive effects of atrazine for pesticidal use without resort to the EDSP. While the assessment came under the force of a court order, the agency was required to act because of the same potential threat to human health and the environment as exists with triclosan. The assessment "outlines a conceptual model for potential future studies that could provide information to resolve inconsistencies and address gaps in the existing knowledge base that currently preclude establishing a definitive characterization of atrazine's effects on amphibian development."[31]

2. Bacterial Resistance Caused by Triclosan Use is a Major Health Threat

EPA states in the RED 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."[32] To the contrary, however, our previous comments pointed to several peer-reviewed studies highlighting the concerns many scientists have with regard to triclosan's role in antibacterial resistance.

These studies also outline a connection between antibacterial resistance and antibiotic resistance. For example, a study by Levy concluded not only that antibacterial products used in the home have no health benefits but also that "use of these products

[30] Office of Prevention, Pesticides and Toxic Substances, Office of Pesticide Programs, Environmental Fate and Effects Division, *White Paper on Potential Developmental Effects of Atrazine on Amphibians*, May 29, 2003.
[31] *Id.* pp, 6, 58-60, 93-95.
[32] RED, p. 40.

may change the environmental microbial flora."[33] Research findings by Schweizer showed that triclosan resistance mechanisms include target mutations, increased target expression, active efflux from the cell, and enzymatic inactivation/degradation. These are the same types of mechanisms involved in antibiotic resistance and some of them account for the observed cross-resistance with antibiotics in laboratory isolates. Therefore, concludes Schweizer, "there is a link between triclosan and antibiotics, and the widespread use of triclosan-containing antiseptics and disinfectants may indeed aid in development of microbial resistance, in particular cross-resistance to antibiotics."[34] Research by Yazdankha, Scheie, Hoiby, *et al* concludes from a review of the literature that "widespread use of triclosan may represent a potential public health risk in regard to development of concomitant resistance to clinically important antimicrobials."[35]

In spite of important research findings such as those just described, however, EPA chose to take an approach that is the complete opposite of the precautionary principle. Thus, the agency requires that the connection between antimicrobial resistance and antibiotic resistance be "expressly proven,"[36] 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

[33] Levy, SB, *Antivacterial Household Products: Cause for Concern,* Emerging Infectious Diseases 7 (3, Supplement) 512-515. (2001); See also, Levy, S.B., *Antibiotic and antiseptic resistance: impact on public health.* Pediatr Infect Dis J, 2000. 19(10): p. S120–2.
[34] Schweizer, H.P., *Triclosan: a widely used biocide and its link to antibiotics.* FEMS Microbiology Letters, 2001. 202(1): p. 1-7
[35] Yazdankhah, S.P., et al., *Triclosan and antimicrobial resistance in bacteria: An overview.* Microbial Drug Resistance-Mechanisms Epidemiology and Disease, 2006. 12(2): p. 83-90.

[36] RED, p. 40.

Resistance.[37] (Task Force) EPA even admits that "none of the goals [of the Task Force] are associated with a specific active ingredient." [38]

EPA's approach to this issue is neglectful and an unnecessary threat to public health. The reregistration of triclosan at this time may have dire consequences for the successful treatment of illness and disease in the future. Furthermore, the problem of resistance disproportionately affects vulnerable populations, including infants and children, the elderly and the immuno-compromised. The widespread use of triclosan enhances bacterial resistance and in so doing reduces its effectiveness where it is needed most--in medical facilities. We urge the agency to take a precautionary approach so as to prevent unreasonable risk when considering the uses of triclosan as they impact antibacterial and antibiotic resistance in health care facilities.

3. NHANES Data on Triclosan Exposure is Insufficient as the Sole Basis for Risk Assessment

Data from the National Health and Nutrition Examination Survey (NHANES)[39] were used to determine population exposures to triclosan in the risk assessment chapters of the RED. We believe that the use of NHANES data is useful only as a *supplement* to the risk assessment process. Certainly, it is commendable that the agency 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.

Urine Testing is Inadequate Because Triclosan Accumulates in Fatty Tissue

[37] *Id.*
[38] *Id.*
[39] NHANES data for triclosan can be found at http://www.cdc.gov/nchs/nhanes.htm.

Measurements of triclosan under NHANES are based on concentrations in spot urine samples.[40] In this regard, it is significant that triclosan, being a *lipophilic* chemical, will accumulate in fatty tissues. Due to this lipophilic nature, it has been found in breast milk. Urine is not the appropriate fluid to *quantitatively* assess triclosan exposure, though it does provide useful *qualitative* information on population exposure to triclosan. Quantitative estimates require more detailed testing, including testing using breast milk, blood, and fat tissue sampling. Quantitative estimates performed in a highly representative sample of individuals would provide more substantial information to establish the quantitative population exposures to these chemicals.

We recommend that in order to make this biomonitoring process more robust, in the case of triclosan, evaluation of breast milk, blood and fat tissue should also be conducted alongside urine in order to capture total human exposures to triclosan. There are numerous peer-reviewed studies detailing the accumulation of triclosan in human fatty tissue that can assist the agency in this measure. In fact, the ongoing testing of breast milk may well be the most accurate indicator of dietary risk for nursing infants and children. As such, we encourage EPA to make breast milk screening for triclosan a regular part of an annual risk assessment, either as part of the NHANES survey or through additional risk assessment research.

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

[40] Risk Assessment, p. 27.

products that have entered the market since 2003. While the NHANES study offers an impressive glimpse of population-level health and nutrition, the data are not analyzed or made publicly available in a timely enough manner to remain EPA's gold standard for risk assessment.

Food Contamination Must be Assessed by EPA

EPA's RED and its *Dietary Risk Assessment for Triclosan for the RED Process*[41] (Dietary Risk Assessment) concluded that "[n]one of the indirect food contact scenarios appear to exceed [the] Agency's level of concern."[42] The agency acknowledges 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)."[43] Nevertheless, "no residue chemistry data based on [agency guidelines] were submitted nor was it requested."[44] In response to many of our comments previously submitted expressing concerns regarding triclosan in food and water aggregate risk assessments, the agency pointed out that the NHANES data captured triclosan exposures.[45] The agency recognizes that if residues are likely in food or drinking water, that dietary risk assessments are needed. In keeping with this, we see it fit that separate dietary exposure and risk assessments be conducted for the human consumption of fish and shellfish, which have been shown to accumulate triclosan in their tissues.[46] The failure to perform a dietary risk assessment on triclosan-

[41] EPA's *Dietary Risk Assessment for Triclosan for the RED Process, August 11, 2008.* (Dietary Risk Assessment)
[42] Dietary Risk Assessment. (unpaginated)
[43] RED, p. 15.
[44] Dietary Risk Assessment.
[45] RED, p. 15.
[46] 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 2004. 38: p. 390-395; Miller, T.R., *Fate of Triclosan and Evidence for Reductive*

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.[47] While NHANES may indeed capture many use patterns of triclosan, we feel it is important to separately evaluate the dietary risk from the consumption of food and drinking water indirectly contaminated by triclosan.

On a related matter, the agency is aware that triclosan-contaminated sewage sludge or biosolids may be used for land application. Recent studies suggest that high levels of triclosan remain in waste-water treatment-plant (WWTP) effluent destined for land application. Thus we feel that that EPA has an obligation to investigate whether current fertilization and farming practices introduce triclosan into the food chain via cow's milk and meat and similar agricultural products.

B. **EPA Failed to Evaluate Major Degradates**

Triclosan is known to form major degradate carcinogenic and persistent toxic compounds when placed in water and exposed to sunlight.[48] These degradates of triclosan pose additional dangers to the already substantial ones threatened by triclosan itself. Yet, EPA failed to conduct risk assessments of these major degradates. And this despite the fact that the European Union has listed such degradates as 2,4-dichlorophenol

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Dechlorination of Triclocarban in Estuarine Sediments. Environ. Sci. Technol., 2008. 42(12): p. 4570–4576.

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

[48] See, Aranami, K. and J.W. Readman, Photolytic degradation of triclosan in freshwater and seawater. Chemosphere, 2007. 66(6): p. 1052-1056. Lores, M., et al., Confirmation of the formation of dichlorodibenzo-p-dioxin in the photodegradation of triclosan by photo-SPME. Analytical and Bioanalytical Chemistry, 2005. 381(6): p. 1294-1298. Sanchez-Prado, L., et al., Monitoring the photochemical degradation of triclosan in wastewater by UV light and sunlight using solid-phase microextraction. Chemosphere, 2006. 65(8): p. 1338-1347. Canosa, P. Rodriguez, I, Rubi, E and Cela, R., Determination of Parabens and Triclosan in Indoor Dust Using Matrix Solid-Phase Dispersion and Gas Chromatography with Tandem Mass Spectrometry, Analytical Chemistry, 2007 79(4): 1675-1681 (Triclosan may have gotten into the dust not only through the use of personal care products, but also through direct leaching from plastic materials and textiles containing triclosan.).

(DCP) as a potential endocrine disruptor[49] and EPA has named it a "priority pollutant."[50] More particularly, we note that CWA Sections 301, 306 and 402 provide for the regulation of effluent pollutant discharges, and Section 303 of that Act imposes water quality standards. Again, as we have observed earlier, lack of coordination and responsible action within the agency has produced ineffective regulation, including a failure to identify and address cumulative risks to the environment caused by triclosan usage.

In response to our comments submitted regarding triclosan's degradation products, the agency states in their document entitled, *Response to Public Comments on the Triclosan Preliminary Risk Assessment*, that "it is not accurate to assume the dioxin congeners, dichlorophenols or other contaminants in the environment are the sole result of any degradation of triclosan."(p30) While this may be true if there were uncertainties concerning triclosan's degradation products, it is disingenuous when science has already determined which degradation products belong to triclosan. In fact, in EPA's *Revised Environmental Fate Science Chapter* in support of triclosan's RED, it is stated that "one major transformation product was identified, DCP (2,4-dichlorphenol), which was present at a maximum of 93.8-96.6% of the applied dose at 240 minutes post treatment," for aqueous photolytic degradation. The document goes on to identify methyl triclosan as another major transformation product.

Further, as already noted herein, DCP or 2,4-dichlorophenol has also been identified as a degradation product of triclosan in independent peer-reviewed studies as

[49] European Commission Dg Env., Annex 13: List of 146 substances with endocrine disruption categorisations prepared in the Expert meeting. BKH Consulting Engineers, 2000(Delft, Netherlands).
[50] US EPA. *Priority Pollutants / 307(a) Toxics*. Water Science 2008 [cited 2008 July 1]; Available from: http://www.epa.gov/waterscience/methods/pollutants.htm.

well. It is therefore puzzling that the agency dismissed our calls for the evaluation of triclosan's degradates, and completely ignored that when in water and with sunlight, triclosan can transform (93.8-96.6%) into DCP. The agency must conduct risk assessments for these major degradates

C. EPA's Failure to Consider Cumulative Risks is a Direct Violation of the Food Quality Protection Act and Its Inaction Sets the Stage for Violations of Other Federal Statutes

EPA acknowledges that it failed to consider cumulative risks in the triclosan RED. While noting its duty to make such an assessment under the Food Quality Protection Act, the agency states that it has not made a finding of the existence of "common mechanisms of toxicity" such that a cumulative risk assessment would be necessary. The agency further identifies the substance triclocarban having been detected along with triclosan in the environment and having "some structural similarity," but EPA concludes they belong two "two different classes." [51] EPA concludes further that currently there is "insufficient evidence characterizing major biochemical events between triclosan and triclocarban to suggest that these two chemicals share a common mechanism of toxicity."[52] In a similar vein, EPA states that it "can reasonably conclude that the antimicrobial uses of triclosan … are unlikely to contribute significant quantities of triclosan into household wastewater and eventually to surface water."[53]

In drawing these and other similar conclusions, EPA has blatantly violated the express requirements of the Food Quality Protection Act and numerous other laws. Such

[51] RED, p. 35.
[52] RED, p. 35.
[53] RED, p. 32.

a lax and incomplete approach to assessment creates numerous serious threats to human health and the environment. The United States Geological Survey's (USGS) study of the occurrence of pharmaceuticals, hormones and other organic wastewater contaminants in water resources found that triclosan is one of the most detected chemicals in U.S. surface waters. A principal reason for this is that most triclosan products are wash down drains and contaminate waterways and water treatment facilities. Therefore, for EPA to consider only the registered uses of triclosan and not consider other sources (including FDA-approved uses) is a flagrant failure to consider health and environmental values seriously.

D. It was Improper and Illegal for EPA not to have Provided for Protection of Threatened and Endangered Species

EPA acknowledges that a "preliminary analysis indicates there is a potential for triclosan use to overlap with listed species and a more refined assessment is warranted, to include direct, indirect and habitat effects."[54] Yet, the agency failed to provide that more refined assessment. After some description of certain "established procedures" for evaluation of ESA issues, the agency simply observes that an analysis will be performed later, "under the Registration Review" program.[55]

From the standpoint of the agency's mandate to protect the environment, EPA's decision was deeply flawed and irrational. Obviously, until whatever point in the future some assessment is performed on triclosan's effect on threatened and endangered species and their habitats, a potentially serious and imminent danger to the environment will

[54] RED, p. 33.
[55] *Id.*

simply be allowed to exist. This is unacceptable and EPA has failed to perform its duty as mandated by law.

Conclusion

There have been some improvements made to triclosan's Risk Assessment. In particular, these include the assessment of exposures for children under 6 years old, assessments of inhalation routes, and the use of modeling techniques to assist in environmental fate characterization. At the same time, however, the EPA still 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 still not proven that triclosan poses "no unreasonable adverse effects" to human health and the environment.

We encourage the EPA to consider evaluating efficacy trials to assess the reasonableness of the hazard in light of triclosan registered uses in plastics, textiles, fabrics and vinyl. Due to the persistent exposure of triclosan through these products, it is of critical importance that the Agency determines the added value of this chemical before making the final decision to reregister triclosan. Finally the reregistration of triclosan does not uphold that standards of the 1996 Food Quality Protection Act, which sought to estimate total risk over the life course in order to improve public health. Because the prevalence of triclosan in consumer products has risen dramatically over the last decade, the scientific data do not yet reflect the potential long-term effects of prenatal and

childhood exposure to triclosan and triclosan-contaminated household dust, drinking water and food sources.

We appreciate this opportunity to submit these Comments, and we stand ready to participate in whatever way will promote the cause of protection of human health and the environment.

On behalf of:

Beyond Pesticides
Food and Water Watch
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