July 7, 2008

OPP Public Regulatory Docket (7502P)
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington DC 20460

RE: Docket Identification No.: EPA-HQ-OPP-2007-0513
Triclosan Risk Assessment

Dear Sir/Madam:

We appreciate the opportunity to comment on the Environmental Protection Agency's (EPA) Risk Assessment for the Reregistration Eligibility Decision (RED) for triclosan. These comments are submitted on behalf of Beyond Pesticides and the following groups (list of groups).

We firmly believe that the continued use of triclosan, a chlorinated compound that bioaccumulates in people and the environment, poses unreasonable risks to human health and the environment, based on information both cited by EPA in its RED and supplemented by additional scientific findings overlooked by the agency. Due to the dangers associated with its routine use and fate, and the dangerous consequences for human health, wildlife and the environment, EPA should cancel registered non-medical uses of triclosan.

Triclosan is a synthetic, broad-spectrum antimicrobial chemical that is currently used extensively in a wide range of consumer products. The chemical has exploded on to the market because of limited efforts by EPA and FDA to restrict its uses and, as a result, exposure to triclosan is escalating daily in virtually all areas of residential, commercial, consumer and personal care products. As a high production volume (HPV) chemical, over one million pounds of triclosan is used in the United States each year.[1] EPA's regulatory jurisdiction for the antimicrobial triclosan includes latex, plastics, mulch, floors, shower curtains, textiles and toys, to name a few. EPA also recognizes that only a small proportion of triclosan uses are regulated under the *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA), while the majority of the uses for triclosan fall under the jurisdiction of the U.S. Food and Drug Administration (FDA). These include various household products such as hand soaps, toothpastes, deodorants and antiseptics, etc. According to the Preliminary Risk Assessment for the Reregistration Eligibility Decision (RED) Document for triclosan, exposures from all uses (under the authority of both EPA and FDA) have been considered in the aggregate risk assessment to support the Reregistration Eligibility Decision.

We support the agency's position that it must conduct an aggregate risk assessment for all triclosan products, but find that the assessment is deficient and therefore underestimates risk.

These deficiencies arise from extrapolating biomonitoring data, dismissing residues in food, and not applying a formal *Food Quality Protection Act* (FQPA) analysis.

Our comments identify significant areas of concern in addition to EPA's flawed analysis and the misapplication of standards in law, including (i) deficiencies in attention to the scientific literature in areas of dietary exposure, water contamination, and wildlife poisoning, (ii) extensive uncertainties given no or limited data and missing studies or reviews, and (iii) a failure to consider product efficacy and the serious and growing secondary health impacts associated with bacterial resistance, rendering triclosan and certain antibiotics ineffective for critical medical uses.

I. Triclosan Is Hazardous for Human Consumption in Food and Water.

EPA is incorrect in not conducting a formal *Food Quality Protection Act* (FQPA) analysis simply because there are "no food use tolerances for triclosan." In fact, EPA recognizes that triclosan residues pose a potential hazard to humans through the food and water supply. The agency has a duty to establish triclosan food tolerances and "acceptable" water levels based on triclosan use patterns. These use patterns, as directed by product labels, directly result in triclosan residues in the food and water supply. The agency acknowledges that triclosan use patterns result in exposure through food and water and therefore they should be subject to an EPA exposure and risk assessment under a formal FQPA analysis.

One of EPA's registered triclosan products, EPA Reg #2829-139 (Vinyzene dp 7000), is incorporated into cutting boards. Researchers have found that triclosan can migrate from kitchenware info food, including from a treated cutting board. "[E]xperiments performed with TCS-containing kitchenware and foodstuff samples confirmed the capability of this bactericide to migrate from treated surfaces to food."[2] EPA should not register any uses of triclosan that come in contact with food before exposures are adequately assessed and a food use tolerance set.

In stating that there are "no existing food use tolerances for triclosan," and that "a formal FQPA analysis is not needed for this chemical,"(p8)[3] EPA maintains that, "[T]he Agency is concerned with such widespread detection of triclosan and triclosan methyl residues because such residues may result in potential adverse effects to humans and/or nontarget organisms, including fish, birds, plants, algae, or other organisms." In addition, EPA has identified numerous outstanding data gaps. (p22)[4] The agency's concerns have been confirmed in recent scientific research detailing the presence of triclosan and its residues within fish,[5] establishing an important source of dietary exposure for the public.

Under FQPA, "a pesticide chemical residue in or on a food shall be deemed unsafe…" 21 USC 346a(a)(1), unless EPA sets a tolerance for the chemical, or grants exemptions from the requirement to set a tolerance. The agency, in failing to account for exposures to contaminated fish in its dietary risk assessment,[6] and in light of this statutory stipulation, should deem triclosan and its residues as unsafe in food (such as fish and shellfish, for example), given that no known tolerance has been set and no exemption has been granted.

The presence of triclosan in surface waters poses a dietary risk through drinking water. Triclosan is not completely removed from treated water[7-9] and, unlike wastewater, most surface

water runoff that enters storm drains is untreated and directly flows into creeks and rivers, which supply the drinking water for many municipalities across the U.S. Even though the agency has noted that this dietary exposure should be included in its aggregate risk assessment,[3] EPA has not explicitly recognized and evaluated this pathway and associated residues in its aggregate risk assessment. Given the EPA's duty under FQPA, a formal FQPA analysis should be conducted to include drinking water.

II. Triclosan Is Associated with Increased Bacterial Resistance to Antibiotics and Antibacterial Products.

The agency, in its analysis, has ignored the secondary public health threat caused by triclosan because its widespread use enhances bacterial resistance and in so doing reduces the effectiveness of triclosan and antibiotics needed for medical uses. This poses a potential and serious public health crisis that EPA cannot ignore.

FIFRA states that EPA may not register a pesticide unless the chemical will perform its intended function without causing any "unreasonable adverse effects on the environment" [7 USC § 136a(c)(5)(c)], and that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." [7 USC § 136a(c)(5)(d)] 'Unreasonable adverse effects on the environment' is defined under 7 USC § 136(bb) as "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide."

The agency, however, has not evaluated or recognized that triclosan, in its capacity as an antibacterial substance, poses real and substantial risks to the public in its role in promoting bacterial resistance and cross-resistance to clinically important antibiotics.

Since 2000, a number of studies have verified the occurrence of triclosan resistance among a variety of microorganisms. Evidence is mounting that links the use of triclosan-containing products with the promotion of bacteria resistant to antibiotic medications and antibacterial products.[10, 11] Resistance effects have been shown at low, bacteriostatic and sub-biocidal levels.[12] Triclosan resistant strains of *Escherichia coli* and *Salmonella enterica* have already been identified.[13-15] Of major concern is the possibility that triclosan resistance may contribute to reduced susceptibility to clinically important antimicrobials, due to either cross-resistance or co-resistance mechanisms. Studies examining the mechanisms through which triclosan resistance arises have identified gene mutations, increased target expression, and enzymatic action as pathways leading to resistance.[11, 13, 14, 16] According to Stuart Levy, M.D., Tufts University School of Medicine, these mechanisms lead to a transfer of resistant genes that fosters antibiotic resistance, some of them accounting for the observed cross-resistance with antibiotics.[13, 17]

These studies indicate that extensive use of triclosan provides a suitable environment for the emergence of antimicrobial drug–resistant species, even at very low concentrations.

EPA-regulated products, like cutting boards, counter tops, sponges, toothbrushes, etc., expose bacteria and other microorganisms to long-term, low levels of triclosan, which promote resistance, according to the literature. Recent appearances of drug resistant super bugs, like

methicillin-resistant *Staphylococcus aureus* (MRSA),[12, 13] illustrate the importance of conducting a full evaluation of the impacts of triclosan residues left by triclosan-treated products.

The increasing emergence of drug and antibacterial resistant microorganisms is a direct threat to public health and the environment. It is therefore of the utmost importance that the agency determines that triclosan does pose "unreasonable risks" and reconsider its registration.

III. EPA Fails to Conduct an Adequate Aggregate Risk Assessment.

The use of biomonitoring (urine) data does not release the agency of its responsibility to conduct its own aggregate risk assessment for individual EPA and FDA regulated uses of triclosan. These uses, and combination of uses, are not fully captured when using the National Health and Nutrition Examination Survey (NHANES) to extrapolate individual exposure to triclosan. In fact, EPA acknowledges that the NHANES data is based on "consumer use of the various triclosan products" and is "actual"(p9) for the population surveyed in the survey. This does not fulfill the agency's responsibility to assess the potential aggregate exposure to all the registered uses. The NHANES data also fails to take into account exposures for infants, children, and in utero exposures, which is unacceptable given the evidence that triclosan is in human fatty tissues. Biomonitoring data can supplement, but does not substitute for, aggregate risk assessment in a laboratory setting with controlled dosing. EPA acknowledges that, "Converting spot urine concentration [from NHANES] to dose is a difficult endeavor."(p9) Beyond that, the agency must consider fatty tissue residues, which has not been done.

IV. Risk Assessment Conclusions Are Clouded by EPA-Stated Uncertainties.

EPA, in its unequivocal stance that triclosan exhibits no risk of concern, accepts high degrees of uncertainty throughout its analysis, uncertainties that establish a cloud over its conclusions. There are a series of deficiencies and limitations noted in the document that do not seem to affect the agency's determination to allow the triclosan market to grow unrestricted. The acknowledgment of serious data deficiencies and "no risk of concern" conclusions may be taken as an attempt to absolve the agency and its regulators from responsibility of a future when adverse effects are linked to the widespread and growing use of this chlorinated, bioaccumulative chemical, clearly associated with environmental and food contamination, serious bacterial resistance and cross-resistance with antibiotics.

Some of the uncertainty statements that are found throughout the Preliminary Risk Assessment for the Reregistration Eligibility Decision (RED) document include (emphasis added):

- Uncertainties associated with dose conversion for the aggregate assessment for triclosan arise from using the biological monitoring data from NHANES... "these uncertainties are balanced (and *perhaps* even offset) by..." by several factors listed. (p22)

- "The NHANES results *are believed to be representative* of a range of acute to chronic exposures to children and adults because of the relatively short half-life of triclosan in urine (i.e., 11 hours) and the often daily use of triclosan products such as hand soaps and toothpaste." (p22)

- "There are several *data limitations and uncertainties* associated with the occupational handler and post application exposure assessments…" (p30) and include: (1) Surrogate dermal and inhalation unit exposure values, which had *poor data quality* and require that confirmatory data be submitted to support the occupational scenarios. (2) The quantities handled/treated were estimated since no standard values were available for some [occupational] scenarios. These estimates could be further refined from input from registrants.

- Acute toxicity testing with estuarine and marine organisms was not required for triclosan because end-use products are not intended for direct application to the marine/estuarine environment or effluent containing the active ingredient is *not expected to reach this environment*. As a result, "*No studies have been submitted to fulfill these data requirements*." (p35) (However, literature has found that triclosan does indeed reach the estuarine environment via effluent and other surface runoff. Therefore, this data gap is unacceptable.*)*

- Algal toxicity tests have been "*partially fulfilled*." Studies on the rooted freshwater macrophyte rice (*Oryza sativa*) *have not been submitted*. (p37)

- "There were *no acceptable acute toxicity studies* for freshwater invertebrates or estuarine and marine organisms nor were there any acceptable chronic toxicity studies available for aquatic organisms. Therefore, *risk to these species cannot be assessed*." (p40)

- The agency has identified that "there is a potential for triclosan use to overlap with listed [endangered] species and that *a more refined assessment is warranted*, to include direct, indirect and habitat effects." However, "[T]his analysis has not been conducted for this assessment. An endangered species effect determination will not be made at this time." (p41)

V. Triclosan Exposures and Health Risks Not Adequately Assessed.

Based on population-based biological monitoring data, conducted by the NHANES,[18] the agency concluded that, "[T]he aggregate risks to triclosan from all uses (EPA and FDA) do not trigger a risk of concern."(p9)[3] However, even though this study documented the prevalence of triclosan among the U.S. population and reflects high levels of human exposure, the agency has not sufficiently evaluated *all* human exposures from products that come under its jurisdiction.

People are exposed to triclosan mainly via dermal absorption[19] and such exposures can result in contact dermatitis, skin irritation and photoallergic contact dermatitis (PACD).[20-23] Residential dermal exposures to triclosan arise due to its use on treated articles such as mattresses, clothing, plastic toys, sponges, countertops, etc. However, in its Occupational and Residential Exposure Assessment, the agency fails to take into account residential exposure to treated articles such as countertops, floors and paint that occur over the long-term (chronic). To add to the deficiency, triclosan treated mattresses are also not assessed separately and the agency states, " Triclosan treated mattresses are not assessed separately but are not of concern as they are treated at the same concentration as the textiles/clothing."(p18)[24] The agency has evaluated

short-term and intermediate dermal exposures for textiles, and short-term exposure durations for child exposure (dermal and oral) to toys.[24] Whereas it is feasible that textiles may result in short-term to intermediate exposures, treated mattresses should undoubtedly be assessed for long-term (chronic) exposures, given that percutaneous absorption of triclosan occurs,[25, 26] which can lead to skin irritation and dermatitis, and whose long-term (chronic) effects in humans are still uncertain.

The chemical structure of triclosan closely resembles non-steroidal estrogens and because of this, has the ability to act as an endocrine disruptor. It induces changes in the thyroid hormone-mediated process of metamorphosis of the North American bullfrog, and alters the expression profile of the thyroid hormone receptor, even at concentrations as low as 0.15ug/L.[27-29] In fact, studies have shown that triclosan does indeed have androgenic[28, 30] and estrogenic activity.[30, 31] There is evidence that triclosan may also affect the central nervous system,[32] the immune system,[1] and renal toxicity has been observed in laboratory animals.[33]

According to the risk assessment, EPA did not consider the endocrine disrupting effects of triclosan because the development of an Endocrine Disruptor Screening Program (EDSP) has not been completed. As a consequence, it neglects analyzing an entire category of potential adverse health effects. In fact, the risk assessment omits a group of studies that, taken together, suggest that triclosan may be an endocrine disrupting chemical, capable of interfering with multiple hormones controlling reproduction and neurodevelopment.

There is precedent for the agency to consider endocrine disrupting effects in a human health risk assessment in the absence of a final EDSP. For example, in the RED for atrazine, the agency examined the potential endocrine disrupting effects of atrazine on amphibians, undermining any agency claim that existing studies of the endocrine disrupting effects cannot be considered in its human health risk assessments. Accordingly, given the studies suggesting that triclosan has the potential to cause endocrine disrupting effects, EPA should have quantitatively incorporated these endpoints in its risk assessment of triclosan.

As a lipophilic chemical, triclosan bioaccumulates in fatty tissues. Studies have found concentrations of triclosan in three out of five human milk samples at concentrations ranging from 5.8ng/g to 11ng/g[34, 35]as well as in umbilical cord blood of infants,[36] demonstrating that babies are exposed to concentrations of triclosan in and out of the womb. These results raise concerns for the developing fetus during vulnerable periods of development, and elevate concerns regarding the bioaccumulative and endocrine disruptive potential of triclosan. Another recent study has identified triclosan in indoor dust at an average value of 702 ng/g, a level similar to what is reported for this compound in municipal sludge.[7] This new research adds another facet to the routes of human exposure that the agency has not considered.

VI. Occupational Protection is Deficient.

EPA identifies severely elevated occupational exposure risks for commercial painters and material preservative use in paper, and then assumes full protection with personal protection equipment. At the same time that EPA documents severely excessive occupational hazards, it points out that "the use of chemical resistant gloves on the label is impractical," but in contradiction assumes that requirements for personal protection equipment (PPE) will be

followed and virtually eliminate exposure and risk. The agency has no evidence that PPE is practical, will be used, and is effective.

VII. Failure to Consider Chemicals with a Common Mechanism of Toxicity.

EPA acknowledges that it did not carry out a critical cumulative risk assessment to assess triclosan's effects in combination with other chemicals that have a common mechanism of toxicity. This requirement in FQPA, adopted in 1996, for which EPA issued guidance for public comment in January 2002 (67 FR 2210-2214), has not been carried out for the triclosan RED 12 years after taking effect. According to EPA, "AD [Antimicrobial Division] did not perform a cumulative risk assessment as part of this RED for triclosan because AD has not yet initiated a review to determine if there are any other chemical substances that have a mechanism of toxicity common with that of triclosan." (p27)[3] We note that the agency does not seem to take its risk assessment process and scientific integrity very seriously when it chooses to ignore a risk factor that could have dramatic impact on the safety of human health and the environment.

EPA's failure to act is especially deficient because the antimicrobial triclocarban, which is a widely used ingredient in soaps and deodorants, co-occurs in the environment with triclosan[9]. These two chemicals have similar modes of action and is an obvious candidate for common mechanism consideration. EPA must consider the obvious and carry out its responsibility under this RED.

VIII. Triclosan Poses Unreasonable Risks to Wildlife 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. [37] This is because most triclosan product uses (both EPA and FDA uses, such as antibacterial dish liquid) are washed down the drain and contaminate waterways and water treatment facilities.

According to the USGS study, the maximum concentration of triclosan found was 280ng/L (with a median concentration of 40ng/L). The environmental risk assessment conducted by EPA concluded that, based on these observed concentrations, levels of concern were not exceeded for fish or aquatic plants.[3]

Even though research involving triclosan's impact on the environment are new, some studies from the literature have found significant declines in plant communities exposed to triclosan. One study notes that significant reductions in algal biomass for cyanobacteria and *Chlamydomonas* at 150 ng/L of triclosan,[38] a concentration well below the maximum concentration observed in the USGS study. This suggests that algal communities are being impacted at concentrations below those not considered a concern by the agency. Another study confirmed that risks are high, particularly for blue-green algae exposed to antibiotics, and both green and blue-green algae exposed to triclosan.[39] The vulnerability of algae, which are important primary producers within the aquatic environment, to contaminants such as triclosan poses serious consequences for aquatic ecosystems.

Methyl triclosan, a derivative of triclosan, has been detected in fish at concentrations in the range of other persistent organic pollutants.[5] These levels can lead to death in fish and increase vitellogenin production in fish eggs, which suggests estrogenic activity.[8]Triclosan has also been detected in earthworms feeding off the sludge from water treatment plants.[40] In tadpoles, exposure to environmentally relevant concentrations of triclosan (at 150 ng/L) causes changes in thyroid hormone receptor gene expression, a reduction in body weight, increased hind limb development, and a decrease in swimming activity.[5, 8, 27]

The agency has identified several data gaps that are of concern, including algal toxicity tests, acute freshwater invertebrate studies and fish early life-stage (freshwater) studies, which have yet to be submitted by registrants.[41]

Label hazard statements/use recommendations proposed by the agency are (1) "This pesticide is toxic to fish and aquatic invertebrates," and (2) "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit …"[41]

It is unclear why the agency would recommend these label statements, while permitting the uses of products that are recognized as having the ability to adversely impact aquatic systems. Many of the EPA regulated uses involve the discharge of triclosan into waterways. For example, triclosan textiles, when laundered, create effluent that would impact waterways and water treatment facilities. The agency has not only failed to address these impacts in its assessment, but has not fulfilled its responsibility to show that these uses do not pose "unreasonable adverse effects on the environment," as defined in 7 USC §136(bb).

Wastewater treatment plants (WWTP) are impacted by the high concentrations of triclosan in wastewater. Triclosan, being a biocide, removes large populations of beneficial bacteria needed for the water treatment process, placing an economic burden on WWTPs. Triclosan adsorbs onto the sludge/sediment and has been detected in river and estuarine sediments,[8, 42] and impacts aquatic species in sensitive habitat regions.

Sludge from WWTPs is normally recycled and used on agricultural land, further impacting terrestrial microbes essential for healthy ecosystems, as a result of triclosan's activity towards a wide spectrum of microbial species.[8] The above-mentioned reinforces a finding that triclosan does not meet the criteria in 7 USC § 136a(c)(5)(c).

IX. Analysis Fails to Address Endangered Species.

Since the agency acknowledges that it does not have the required data to evaluate impacts on endangered species, it should not issue a final RED, which implies compliance with regulatory standards. EPA states, "A preliminary analysis indicates that there is a potential for triclosan use to overlap with listed species and that a more refined assessment is warranted, to include direct, indirect and habitat effects."(p13)[3] In a footnote, EPA states, "The Agency is making this statement because triclosan and triclosan transformation products are being detected in various environmental components." The agency, similar to other sections where it has not

met its statutory responsibility, simply concludes with the statement, "An endangered species effect determination will not be made at this time."(p13)

X. EPA Fails to Evaluate Major Degradates.

Triclosan in water, when exposed to sunlight, degrades and forms toxic compounds, like 2,8-dichlorodibenzo-p-dioxin (DCDD), dichlorophenols and other similar compounds, [7, 8, 43-45] which are known to be carcinogenic and persistent. Other major degradates, as identified by the agency, include methyl triclosan, which has been shown to bioaccumulate in aquatic organisms and possibly in human beings, as well as 2,4-dichlorophenol (DCP), which is listed by the European Union as a potential endocrine disruptor,[46] and an EPA priority pollutant.[47] Triclosan has also been found to interact with free chlorine, normally occurring in tap water, to form chloroform.[48] The agency has failed to conduct risk assessments for these major degradates and transformation products, which pose substantial hazards beyond those associated with the active ingredient itself.[7]

XI. EPA Fails to Evaluate Triclosan Efficacy and Necessity.

40 CFR 158.640(1) states that efficacy data is waived unless "the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot be observed by the user including but not limited to, microorganisms infectious to man in any area of the inanimate environment..," however, the agency's documents do not indicate the submission of such data. Low concentrations of triclosan in products such as sponges, cutting boards, etc. only serve to increase bacterial resistance, as cited above, and, in turn, threaten human health. In the absence of efficacy data, it is unclear whether these products indeed serve the purpose they are intended for, or whether they serve to exacerbate the problem. With proper hygiene and sanitation, triclosan treated products become redundant.

XII. Regulatory Gaps Leave Uses Unchecked.

Recently, it has become unclear to the public whether EPA or FDA is responsible for regulating many of the consumer products on the market. For example, it has been observed that many dishwashing liquids are labeled 'antibacterial,' and contain triclosan as the active ingredient (e.g. Ajax Antibacterial, Dawn Antibacterial). Upon closer examination, labels state "Fights germs on hands when used as a hand soap." The human and environmental impacts that arise from the product's primary use for dishes have not been accounted for by either agency. The fact that the manufacturer on the label refers only to its antimicrobial effects on hands does not release EPA of the responsibility to evaluate the exposure and health and environmental impacts associated with its primary use on dishes. Certainly, EPA should be concerned about the use pattern of a product such as this on inanimate objects and the possibility of short and long-term dermal and oral exposures to the active ingredient, which is a known and registered pesticide.

Another issue is the reality that many triclosan treated products are exempt from registration because of claims to only protect the product in which it is incorporated. According to the EPA, the Code of Federal Regulations allows an exemption for:

"An article or a substance treated with or containing a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insects or fungus infestation), if the pesticide is registered for such use."[49]

Products such as hairbrushes, hair accessories, and sporting equipment, including helmets, etc., have been identified as containing triclosan but have eluded EPA review for incidental human health effects in the RED. EPA has failed to assess whether human exposures, especially dermal exposures, occur as a result of the use of such products. The RED falls short in not assessing a large number of products on the market to which humans are exposed, with product packaging advertising triclosan components that offer "antimicrobial product protection." While the manufacturer claims product protection, these products' use patterns create human and environmental exposures.

XIII. Incident Reporting Has Been Undermined by EPA.

This document cannot be independently evaluated without a comment about the "no reported incidents for triclosan" comment in the RED, which grows out of a long history of the agency undermining the effective collection of data that could and should inform regulatory action. As the agency knows, the Pesticide Incident Monitoring System (PIMS) was shut down by EPA, thus limiting the agency's access to data from trained sites associated with outreach and data collection efforts. The Centers for Disease Control Poison Control Centers, while important, picks up the most egregious poisonings, usually those caused by accidental ingestion. The FIFRA 6(a)2 "incident" data that EPA collects from pesticide manufacturers has been emasculated by the agency's own guidelines and lack of enforcement, and is deficient by not requiring manufacturers to report all communication with the public on adverse effects of its products. EPA itself, in its *OPP Report on Incident Information,* characterizes the 6(a)2 data as "low to uneven levels of detail, lack of fully automated system difficulty of working with data (need to review hard copies instead of electronic searches)." While it is admittedly challenging to manage an effective database, the agency has not made it a priority and effectively undermined its value, making its "no reported incidents" less than meaningful.

XIV. Conclusion.

A review of the agency's risk assessment documents for triclosan reveals significant issues that have not been fully evaluated or simply ignored. Long-term studies for several registered products (e.g. floors, mattresses) have not been evaluated, even though they realistically create long-term exposures. Growing evidence of triclosan's impact on the environment, especially related to bacterial resistance and resulting health effects, have not been included in the assessment, despite scientific evidence that implicates triclosan in this phenomenon. Its pervasive presence in waterways impacts aquatic organisms and wildlife, and contaminates drinking water supplies. The broad direct and indirect effects of triclosan use in consumer and commercial products, including the effects of the active ingredient, its degradates and contaminants, are ubiquitous, bioaccumulative and multi-generational.

Although the agency acknowledges and includes FDA uses in its assessment, it fails to conduct a full and adequate aggregate risk assessment, evaluate the environmental impacts of the

products under its jurisdiction, such as textiles and clothing, and consider the serious secondary public health threat associated with bacterial resistance and cross-resistance to antibiotics. EPA has not adequately demonstrated, in light of long-standing and recent science, that triclosan poses no unreasonable adverse effects on the environment. As such, its reregistration should be reconsidered and registration denied.

Sincerely,

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(on behalf of the following organizations)

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Allergy & Environmental Heath Association of Québec
Beyond Pesticides Ohio
Breast Cancer Fund
California Safe Schools
Californians for Alternatives to Toxics
Center for Environmental Health
Chemical Sensitivity Disorders Association
Citizens Against Pesticide Exposure (IL)
Citizens Campaign for the Environment
Environment and Human Health, Inc. (CT)
Environmental Health Association of Nova Scotia
Environmental Health Fund
Environmental Health Network
Greenpeace US
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Healthy Building Network
Healthy Child Healthy World
Healthy Communities Project (WI)
Healthy Schools Network, Inc.
Hilltown Anti-Herbicide Coalition (MA)
INFORM Inc.
Informed Choices
Kids for Saving Earth
Lake Michigan Inter-League Group
Lower Susquehanna RIVERKEEPERÂ®
Maryland Pesticide Network

Micah's Mission
National Center for Environmental Health Strategies, Inc.
Natural Resources Council of Maine
Natural Resources Defense Council
Northwest Coalition for Alternatives to Pesticides
Northwest Environmental Defense Center
NoSprayNashville
Oregon Toxics Alliance
Ottawa Environmental Health Clinic
Parents for a Safer Environment (CA)
Peoples' Action for a Safe Environment
Pesticide Action Network North America
Pesticide Watch (CA)
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Sierra Club
Sierra Club Maine Chapter
TEDX (The Endocrine Disruption Exchange)
Toxic Free NC
Women's Environmental Institute (MN)
Women's Voices for the Earth (MT)

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