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May 24, 2010

Division of Dockets Management HFA-305
U.S. Food and Drug Administration (FDA)
5630 Fishers Lane, RM 1061
Rockville, MD 20852

**Re: Safety and Efficacy Review for Additional Ingredients in Over-the- Counter Drug Products for Human Use; Request for Environmental Impact Data and Information.**
**Docket Number: FDA-1996-N-0006**

Dear Sir/Madam:

We are writing to provide comment and data to the U.S. Food and Drug Administration (FDA) regarding the potential environmental impact of amending over-the-counter (OTC) drug monographs to include certain active ingredients including triclosan, which is being proposed for inclusion in the OTC drug monographs; acne and antigingivitis/antiplaque monographs. These comments are a follow-up to the citizen petition submitted July 14, 2009 by Beyond Pesticides, Food and Water Watch and others, which the agency is currently considering. In order for an active ingredient to be included to an OTC monograph, the agency must comply with the National Environmental Policy Act of 1969 (NEPA) and complete an environmental assessment to evaluate any potential environmental impact that may occur if the active ingredient is included in an OTC monograph. The agency has indicated that it is currently evaluating the effectiveness and safety of these ingredients, even though many of these ingredients, especially triclosan, have been used in acne and antiplaque/antigingivitis and other OTC products for decades.

Based on data provided in these comments, as well as the citizen petition submitted in 2009 by Beyond Pesticides, Food and Water Watch and others, the agency must recognize that significant adverse environmental impacts will occur with continued triclosan use, and in so finding, must conclude that the only effective mitigating measure to reduce environmental risks is the exclusion of triclosan from the acne or antiplaque/antigingivitis monographs, and a restriction of triclosan in consumer products in general.

According to 21 CFR 25.31(a) to agency is not required to prepare an environmental assessment (EA) or an environmental impact statement (EIS) if the action on an OTC monograph does not increase the use of the active moiety, and where the environmental concentration at the point of entry into the aquatic environment of the ingredient does not exceed 1ppb (21 CFR 25.31(b)). The use of triclosan in cosmetics, soaps and OTC drug products have increased since the 1990s, and has directly led to triclosan

entering the environment at environmentally relevant concentrations.[1] In fact, triclosan has begun to accumulate and contaminate aquatic and terrestrial organisms, including humans, and has potentially entered the food chain.[2,3] Given these data, the agency must move forward with an EA. The scientific literature indicates that triclosan's use in OTC products must be restricted.

**Responsibilities Under Federal Law**

The purpose of NEPA, to which all federal agencies must comply, is to "promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man; to enrich the understanding of the ecological systems and natural resources important to the Nation" (42 USC § 4321). To ensure that damage to the environment is prevented, the FDA is required under NEPA to consider the environmental impacts of approving drug and biologics applications as an integral part of its regulatory process. NEPA states that the agency shall "include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on -(i) the environmental impact of the proposed action, (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented, (iii) alternatives to the proposed action, (iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and (v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented," 42 USC § 4332(C).

All FDA actions must be assessed for environmental impact unless the action qualifies for categorical exclusion, (21 CFR 25.31). To qualify for an exclusion for human drugs, the action (on the OTC monograph) must not increase the use of the active moiety, 21 CFR 25.31(a) or if the action increases the use of the active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion, 21 CFR 25.31(b). FDA must conduct an EA if extraordinary circumstances indicate that the quality of the human environment may be affected, i.e. "Actions for which available data establish that, at the expected level of exposure, there is the potential for serious harm to the environment," 21 CFR 25.21(a) and "Actions that adversely affect a species or the critical habitat of a species determined under the Endangered Species Act…" 21 CFR 25.21(b).

Because triclosan does not meet the requirement for categorical exclusion, the FDA must conduct an EA in order to comply with NEPA. Triclosan's estimated usage in the U.S. is more than 1,000,000 lb/yr[4] (>300,000 kg/yr)[5] and is growing annually, as is evident by the hundreds of personal care products and cosmetics that contain triclosan. Since triclosan-containing products are directly washed down the drain, use at this level increases the active moiety (as defined in 21 CFR 25.5 ((b)(2)) of triclosan in the environment, and thus the aquatic concentrations of triclosan.

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[1] American Medical Association. 2000. Use of Antimicrobials in Consumer Products. Report 2 of the Council on Scientific Aff airs (A-00).

[2] Adolfsson-Erici, M., M. Petersson, J. Parkkonen, and J. Sturve. 2002. Triclosan, a commonly used bactericide found in human milk and in the aquatic environment in Sweden. Chemosphere 46:1485-1489.

[3] L. Samsoe-Petersen, M. Winther-Nielsen, and T. Madsen, Danish EPA, "Fate and Effects of Triclosan," September 2003.

[4] Miller, T.R. et al. 2008. Fate of Triclosan and Evidence for Reductive Dechlorination of Triclocarban in Estuarine Sediments. *Environ. Sci. Technol. 42;* 4570–4576.

[5] Cantwell, M. et al. 2010. Temporal trends of triclosan contamination in dated sediment cores from four urbanized estuaries: Evidence of preservation and accumulation. Chemosphere 78 ; 347–352

21CFR 25.40 (a) states "….If potentially adverse environmental impacts are identified for an action or a group of related actions, the EA shall discuss any reasonable alternative course of action that offers less environmental risk or that is environmentally preferable to the proposed action." 21CFR25.40(e) "The agency evaluates the information contained in an EA and any public input to determine whether it is accurate and objective, whether the proposed action may significantly affect the quality of the human environment, and whether an EIS or a finding of no significant Impact (FONSI) will be prepared. The responsible agency official examines the environmental risks of the proposed action and the alternative courses of action, selects a course of action, and ensures that any necessary mitigating measures are implemented as a condition for approving the selected course of action."

There is a wealth of data proving that triclosan is a persistent and bioaccumulative pesticide, which results in adverse environmental impacts (21 CFR 25.21(a)). Triclosan poses an imminent threat to aquatic species and the critical habitat of species, (21 CFR 25.21(b)). The evidence continues to demonstrate that triclosan transforms into other, potentially more hazardous substances. Thusly, these commenter's urge the agency to recognize the adverse impacts associated with the continued use of triclosan. Moreover, the FDA must ensure that the human and environmental impacts of triclosan are not made worse by the inclusion of triclosan in the acne or antiplaque/antigingivitis monographs.

**Triclosan In the Aquatic Environment**

As mentioned above, FDA, under 21 CFR 25.21 (a) and (b), must assess triclosan's potential for environmental harm and has requested information to assist its evaluation. Triclosan is used in excess of 300,000kg/yr in products that are washed directly down drains and into wastewater treatment plants. Because the wastewater treatment process does not fully eliminate triclosan, McAvoy et al. (2002) found 3.8 to 16.6 ug/l triclosan in influent wastewater,[6] and Georgia, Kumar et al. (2010) detected wastewater influent concentrations of triclosan as high as 86.16ug/l and 5.37ug/l in effluents.[7] Other concentrations detected range from 1.86-26.8ug/l for influent concentrations and 0.027 – 2.7 ug/l for effluent concentrations of triclosan.[8] Furthermore, the U.S. Geological Survey (USGS) published a study in 2002 identifying concentrations of 2.3ug/l to a minimum concentration 0.14ug/l[9] of triclosan in water samples from 85 streams across the U.S. collected in 1999-2000. Furthermore, Halden and Paull (2005) found 1.6ug/l triclosan in urban streams in the Greater Baltimore region.

The Center for Drug Evaluation and Research (CDER) Guidance on Environmental assessment of Human Drug and Biologic Applications' calculation for the expected introduction concentration (EIC) of the active moiety into the aquatic environment (section III (A) (2)) would yield triclosan in excess of 1ppb in the aquatic environment based on current usage estimates. As evidenced above, triclosan already exists in the environment in excess of 1ppb in surface waters and in both wastewater influent and effluent. These concentrations are at environmentally relevant concentrations that exceed levels of concern

[6] McAvoy, D.C., Schatowitz, B., Jacob, M., Hauk, A., Eckhoff, W.S., 2002. Measurement of triclosan in wastewater treatment systems. *Environ. Toxicol. Chem*. 21;1323–1329.

[7] Kumar KS, Priya SM, Peck AM, Sajwan KS. 2010. Mass loadings of triclosan and triclocarbon from four wastewater treatment plants to three rivers and landfill in Savannah, Georgia, USA. *Arch Environ Contam Toxicol*. 58(2):275-85.

[8] Chalew and Halden. 2009. Environmental Exposure of Aquatic and Terrestrial Biota to Triclosan and Triclocarban. J Am Water Works Assoc. 45(1): 4–13.

[9] Kolpin, D.W. et al. 2002. Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Streams, 1999-2000: A National Reconnaissance. Environ. Sci. Technol. 36; 1202-1211

(LOCs) for aquatic plants.[10]

U.S. Environmental Protection Agency (EPA), as part of its Ecological Hazard and Environmental Risk Assessment for triclosan, compared the highest concentration of triclosan found in U.S. streams (2.3ug/l) to the highest toxicity found for aquatic plants (1.2ug/L) and found the potential for acute risk to these organisms. An evaluation of the effects of triclosan on natural freshwater algae located upstream and downstream of a wastewater treatment plant indicates that a concentration of 0.15 ug/l caused a significant reduction in *Chlamydomonas sp*. (unicellular alga) which the EPA acknowledges calls for further research on shifts in algal communities, reductions in biomass, and effects on higher trophic levels.[11]

Other studies have found that triclosan reduces algal genus richness and impacts both the structure and the function of algal communities in stream ecosystems receiving wastewater treatment plant (WWTP) effluents.[12] Triclosan, being a biocide, exerts a marked influence on algae, which are important organisms (first-step producers) in the ecosystem, and is particularly highly toxic to the green algae.[13] Its prevalence in the aquatic environment can therefore lead to the possible destruction of the balance of the ecosystem. Brian, et al. (2008) confirmed that risks are high, particularly for blue-green algae exposed to antibiotics, and both green and blue-green algae exposed to triclosan.[14] In fact, crustaceans (*Ceriodaphnia dubia)* and algae have been identified as the most sensitive species, susceptible to adverse effects from biocide exposures in the parts-per-trillion (ppt) range.[15]

Aquatic vertebrates are also impacted. Veldhoen et al., in a 2006 study, found that exposure to low levels of triclosan disrupts thyroid hormone-associated gene expression and can alter the rate of thyroid hormone-mediated postembryonic anuran development. These researchers determined that exposures to concentrations of triclosan as low as 0.03 ug/L for 24 hours resulted in altered thyroid hormone receptor mRNA expression. Triclosan at concentrations ranging from 230 to 0.23 ug/l was observed to modify behavior and survivability of young premetamorphic tadpoles of the North American bullfrog, *Rana catesbeiana.* [16] Others have noted that at concentrations of 0.15ug/l triclosan can cause not only changes in thyroid hormone receptor gene expression, but also reductions in body weight, increases in hind limb development, and decreases in swimming activity.[17] Triclosan can also increase the vitellogelin production in medaka (*Oryzias latipes)* eggs at 20 and 100 ug/l, and kill 24-hr-old medaka larvae at

[10] USEPA. 2008. Reregistration Eligibility Decision (RED) Document for Triclosan. Office of Prevention, Pesticides and Toxics. Washington DC

[11] USEPA. 2008. Reregistration Eligibility Decision (RED) Document for Triclosan. Office of Prevention, Pesticides and Toxics. Washington DC

[12] Wilson, B.A. 2003. Effects of Three Pharmaceutical and Personal Care Products on Natural Freshwater Algal Assemblages. *Environ. Sci. Technol*. 37; 1713-1719.

[13] Tatarazako N et al. 2004. Effects of triclosan on various aquatic organisms. *Environ Sci*. 11(2):133-40.

[14] Brain RA, Hanson ML, Solomon KR, Brooks BW. 2008. Aquatic plants exposed to pharmaceuticals: effects and risks. Rev Environ Contam Toxicol. 192:67-115.

[15] Chalew and Halden. 2009. Environmental Exposure of Aquatic and Terrestrial Biota to Triclosan and Triclocarban. *J Am Water Works Assoc.* 45(1): 4–13.

[16] Veldhoen, N., et al. 2006. The bactericidal agent triclosan modulates thyroid hormone-associated gene expression and disrupts postembryonic anuran development. *Aquatic Toxicology*. 80(3): 217-227.

[17] Miller, T.R. et al. 2008. Fate of Triclosan and Evidence for Reductive Dechlorination of Triclocarban in Estuarine Sediments. *Environ. Sci. Technol. 42;* 4570–4576.

higher concentrations,[18] suggesting that triclosan is a weak estrogenic compound with the potential to induce vitellogenin in male medaka. Sub-lethal concentrations of methyl-triclosan, a metabolite of triclosan have also been detected in fish downstream from WWTPs.[19]

Wastewater treatment plants (WWTP) are negatively impacted by the high influent concentrations of triclosan. . Triclosan, being a biocide, removes large populations of beneficial bacteria needed for the water treatment process, placing an economic burden on WWTPs. Many facilities have removal rates of 58– 97% for trickling filter plants and 95–98% for activated sludge plants,[20] due to triclosan's potential to adsorb to sediment and sludge. However, triclosan has been detected in sewage effluents due to incomplete removal during wastewater treatment,[21] resulting in high concentrations of triclosan in sewage sludge.

EPA's Targeted National Sewage Sludge Survey, released in 2009, identified triclosan, and its chemical cousin triclocarban, as the most frequently detected pharmaceuticals, at the highest concentrations in WWTP sludge.[22] This poses grave concern to terrestrial environments since sewage sludge is often recycled and used on agricultural land.[23] Triclosan has also been detected in earthworms living in sludge-recycled land .[24] More information is needed to determine whether triclosan can contaminate crops that are exposed to triclosan-laden sludge.

Triclosan in the aquatic environment, when exposed to sunlight, transforms to toxic compounds, like 2,8-dichlorodibenzo-p-dioxin (DCDD), dichlorophenols and other similar compounds,[25,26,27] some of which are known to be carcinogenic and persistent. Most recently, researchers from the University of Minnesota identified three additional dioxin congeners that result from triclosan's reaction to sunlight

[18] Ishibashi H, et al. 2004. Effects of triclosan on the early life stages and reproduction of medaka Oryzias latipes and induction of hepatic vitellogenin. *Aquat Toxicol.* 67(2):167-79.
[19] Balmer, M. et al. 2004. Occurrence of Methyl Triclosan, a Transformation Product of the Bactericide Triclosan, in fish from Various Lakes in Switzerland. *Environ. Sci. Technol*. 38(2); 390-395
[20] Heidler and Halden. 2007. Mass balance assessment of triclosan removal during conventional sewage treatment. *Chemosphere* 66 ; 362–369
[21] Halden, R.U., Paull, D.H., 2005. Co-occurrence of triclocarban and triclosan in US water resources. Environ. Sci. Technol. 39, 1420–1426, McAvoy, D.C., Schatowitz, B., Jacob, M., Hauk, A., Eckhoff, W.S., 2002. Measurement of triclosan in wastewater treatment systems. *Environ. Toxicol. Chem*. 21;1323–1329, Balmer, M. et al. 2004. Occurrence of Methyl Triclosan, a Transformation Product of the Bactericide Triclosan, in fish from Various Lakes in Switzerland. *Environ. Sci. Technol*. 38(2); 390-395
[22] USEPA. 2009. Targeted National Sewage Sludge Survey. Office of Water (4301T). Washington DC.
[23] Ying GG, Xiang-Yang Y, Kookana RS. 2007. Biological degradation of triclocarban and triclosan in a soil under aerobic and anaerobic conditions and comparison with environmental fate modelling. *Environ. Poll*; 50:300–5.
[24] Kinney C., et.al. 2007. Bioaccumulation of Pharmaceuticals and Other Anthropogenic Waste Indicators in Earthworms from Agricultural Soil Amended With Biosolid or Swine Manure. *Environmental Science & Technology*, 42(6).1863-1870
[25] Aranami, K. and J.W. Readman. 2007. Photolytic degradation of triclosan in freshwater and seawater. *Chemosphere.* 66(6): p. 1052-1056.
[26] Sanchez-Prado, L., et al. 2006. Monitoring the photochemical degradation of triclosan in wastewater by UV light and sunlight using solid-phase microextraction. *Chemosphere.* 65(8): p. 1338-1347.
[27] Lores, M., et al. 2005. Confirmation of the formation of dichlorodibenzo-p-dioxin in the photodegradation of triclosan by photo-SPME. *Analytical and Bioanalytical Chemistry.* 381(6): p. 1294-1298

and the chlorination of the WWTP. [28]Other major degradates 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 a potential endocrine disruptor,[29] and an EPA priority pollutant.[30] Preliminary data has found that triclosan can interact with free chlorine, normally occurring in tap water, to form chloroform.[31] The agency should give these data, on the environmental concentrations of triclosan and its impact on aquatic organisms, serious attention in its preparation of the EA.

Aquatic life is dependent on algal communities, now threatened by concentrations of triclosan found in a significant number of surface waters across the U.S. The agency must move to "ensure that damage to the environment is prevented and eliminated" and restrict the use of triclosan in products under its jurisdiction, as it is tasked under NEPA.

**Triclosan Also Poses A Threat To Public Health**

In addition to the environmental impacts of triclosan, the agency should also consider the body of literature that identifies serious human health risks. Triclosan is an endocrine disruptor that impacts thyroid hormones. The structural similarity of triclosan to thyroid hormones has raised concerns about adverse effects on thyroid homeostasis. A study involving Wistar rats found that although triclosan does not alter androgen-dependent tissue weights or onset of preputial separation, but it does significantly impact thyroid hormone concentrations, specifically suppressing total serum thyroxine (T4) concentrations, in male juvenile rats.[32] In another studying with Long-Evans rats, researchers found dose-dependent decreases in total T4 with triclosan.[33] Triclosan also exhibits antagonistic activity in both estrogen and androgen responsive bioassays.[34] The EPA has also acknowledged that there is "some evidence that triclosan disrupts thyroid hormone homeostasis and interacts with the androgen and estrogen receptors…..and further research may require future modification to the risk assessment [of triclosan]"[35] Based on this data, the agency must move to reduce human exposures to this endocrine disrupting chemical in order to protect human health.

The prevalence on triclosan in the human environment also poses another public health concern that the agency must address. 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

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[28] Buth, J.M., Steen, P.O., Sueper, C., Blumentritt, D., Vikesland, P.J., Arnold, W.A. and K. McNeill. Dioxin Photoproducts of Triclosan and Its Chlorinated Derivatives in Sediment Cores. *Environmental Science & Technology*. Publication Date (Web): May 17, 2010.

[29] 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).

[30] US EPA. *Priority Pollutants / 307(a) Toxics*. Water Science 2008; Available from: http://www.epa.gov/waterscience/methods/pollutants.htm.

[31] Rule, K.L., V.R. Ebbett, and P.J. Vikesland. 2005. Formation of chloroform and chlorinated organics by free-chlorine-mediated oxidation of triclosan. *Environ. Sci. & Tech.* 39(9): p. 3176-3185

[32] Zorrilla, L., et al. 2009. The effects of Triclosan on Puberty and Thyroid Hormones in Male Wistar Rats. *Toxicological Sciences*. 107(1) 56-64.

[33] Crofton, K. et al. 2007. Short-term *in vivo* exposure to the water contaminant triclosan: Evidence for disruption of thyroxine. *Environ Tox. Pharm.* 24(2);194-197

[34] Ahn et al. 2008. *In Vitro* Biologic Activities of the Antimicrobials Triclocarban, Its Analogs, and Triclosan in Bioassay Screens: Receptor-Based Bioassay Screens. *Environ Health Perspect*. 116(9): 1203–1210.

[35] USEPA. 2008. Reregistration Eligibility Decision (RED) Document for Triclosan. Office of Prevention, Pesticides and Toxics. Washington DC

products.[36;37] Resistance effects have been shown at low, bacteriostatic and sub-biocidal levels.[38] Triclosan resistant strains of *Escherichia coli* and *Salmonella enterica* have already been identified.[39,40,41] 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.[42,43] 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.[44]

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 found in many FDA-regulated products and cosmetics. A recent report by the European Commission's Scientific Committee on Consumer Safety determined that low concentrations of triclosan can trigger the expression of resistance and cross-resistance mechanisms in bacteria.[45]

In 2005, the agency's Nonprescription Advisory Panel found no evidence that antibacterial washes were superior to plain soap and water for protecting consumers from bacteria. In the absence of data illustrating triclosan's necessity in consumer products, it is unclear whether these products indeed serve the purpose they are intended for, or whether they serve to exacerbate the growing resistance problem. With proper hygiene and sanitation, triclosan-containing products become unnecessary. We urge the agency to take a precautionary approach when deciding whether to allow OTC antibacterial substances to remain on the consumer market.

As a lipophilic chemical, triclosan bioaccumulates in fatty tissues. Studies have found concentrations of triclosan in three out of five human milk samples as a result of exposure via personal care product containing triclosan,[46,47] as well as in umbilical cord blood of infants,[48] signifying that babies are exposed

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[36] Heath, R., et al. 2000. Inhibition of the Staphylococcus aureus NADPH-dependent enoyl-acyl carrier protein reductase by triclosan and hexchlorophene. *J. Biol Chem*. 275: 654-59.

[37] Aiello, A.E., et al. 2005. Antibacterial Cleaning Products and Drug Resistance. *Emerging Infectious Diseases*. 11(10).

[38] Scientific Committee on Consumer Products- Opinion On Triclosan. Health & Consumer Protection Directorate-General, 2006. Directorate C - Public Health and Risk Assessment(C7 - Risk assessment). European Commission.

[39] Levy, S.B. 2000. Antibiotic and antiseptic resistance: Impact on public health. *Pediatr Infect Dis.* 19(10): S120–2.

[40] Yazdankhah, S.P., et al. 2006. Triclosan and antimicrobial resistance in bacteria: An overview. *Microbial Drug Resistance-Mechanisms Epidemiology and Disease*. 12(2): 83-90.

[41] Davies, A.J., Maillard, J.Y. 2001. Bacterial adaptation to biocides: the possible role of `alarmones'. *J. ospital Infection.* 49(4).

[42] Aiello, A.E., et al. 2005. Antibacterial Cleaning Products and Drug Resistance. *Emerging Infectious Diseases*. 11(10).

[43] Chuanchuen, R., K. Beinlich, T.T Hoang, et al. 2001. Cross-resistance between triclosan and antibiotics in Pseudomonas aeruginosa is mediated by multidrug efflux pumps: exposure of a susceptible mutant strain to triclosan selects nfxB mutants overexpressing MexCD-OprJ. *Antimicrobial Agents and Chemotherapy*. 45: 428-432.

[44] Levy, S.B. 2000. Antibiotic and antiseptic resistance: impact on public health. *Pediatr Infect Dis.* 19(10): S120–2.

[45] SCCS (Scientific Committee on Consumer Safety), Preliminary opinion on triclosan antimicrobial resistance), 23 March, 2010. European Commission, Brussels

[46] Adolfsson-Erici, M., M. Pettersson, J. Parkkonen, and J. Sturve. 2002. Triclosan, a commonly used bactericide found in human milk and in the aquatic environment in Sweden. *Chemosphere*. 46: 1485-1489.

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. Researchers from the Centers for Disease Control and Prevention found triclosan in the urine of 75 percent of the U.S. population, with higher levels found in older and wealthier Americans.[49] Another study has also identified triclosan in indoor dust at levels similar to what is reported for triclosan in WWTP sludge.[50]

**Alternative to the Proposed Action**

Although the proposed applications for triclosan under consideration - acne and antigingivitis - have been on the market for decades, the agency only now moves to prepare an EA. As the agency conducts this research, it must be mindful that these product are washed directly down the drain (e.g. toothpaste, acne face wash etc), resulting in triclosan's entry into the environment. According to 21 CFR 25.40(a), the agency's EA "shall discuss any reasonable alternative course of action that offers less environmental risk or that is environmentally preferable to the proposed action." The most environmentally sound course of action is to prohibit uses of triclosan in these products (acne and antiplaque/antigingivitis), and other triclosan-containing consumer products which fall under FDA's jurisdiction.

As mentioned, data is mounting which show that triclosan does pose unreasonable risks to the aquatic and human environment. The agency must find that the "environmentally preferred option" is to remove triclosan from acne, antigingivitis/antiplaue and other OTC consumer products.

**Conclusion**

We have provided the agency with the most current available scientific data. These data illustrate that the current regulated uses of triclosan result in environmental contamination of surface waters at concentrations above 1ppb. Triclosan is found in over 50% of US waterways at environmentally relevant concentrations where it impacts amphibians and fish, as well as important algal communities. Triclosan is found in human urine, breast milk and umbilical cord blood where as a result of its potential to impact the thyroid hormone, can cause unknown and irreparable effects to human health.

We expect that the EA, and the agencies findings from the ongoing investigation of triclosan, will lead FDA to restrict the use of triclosan in OTC products. This is the only directive that would ensure the prevention of further environmental and human harm. It is also the only course of action that will also, "ensure that damage to the environment is prevented and eliminated" and restrict the use of triclosan in products under its jurisdiction, as it is tasked under NEPA.

Thank you for your consideration of these comments.

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[47] Allmyr, M., et al. 2006. Triclosan in plasma and milk from Swedish nursing mothers and their exposure via personal care products. *Science of The Total Environment*. 372(1): 87-93.

[48] Greenpeace and WWF. 2005. *A Present for Life: Hazardous chemicals in umbilical cord blood.* [Available from: http://eu.greenpeace.org/downloads/chem/Umbilicalcordreport.pdf>.

[49] Calafat, A.et al. 2008. Urinary Concentrations of Triclosan in the U.S. Population: 2003–2004. *Environ Health Perspect* 116:303–307

[50] Canosa, P., Rodrıguez, I., Rubı´ E. and R. Cela. 2007. Determination of Parabens and Triclosan in Indoor Dust Using Matrix Solid-Phase Dispersion and Gas Chromatography with Tandem Mass Spectrometry. *Analytical Chemistry.* 79: 675-1681.

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