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Office of Pesticide Programs
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Regarding: EPA's Decision to Support Re-registration of Triclosan
Docket EPA–HQ–OPP–2007–0513

Environmental Working Group (EWG) is writing to express our concerns about the Environmental Protection Agency (EPA)'s decision to re-register the antimicrobial chemical triclosan for continuous use in commerce. Our organization focuses on potential human and environmental health risks from exposures to hazardous chemicals that contaminate food, water, and the environment, or that are used as ingredients in consumer products. In our earlier comments about the EPA's draft risk assessment for triclosan we indicated to the Agency that this potent pesticide might pose unacceptable risks to children's health and the environment (Sutton 2008).

EWG applauds EPA's final decision to re-assess triclosan toxicity in 2013, a timeframe that will allow the Agency to respond to the rapidly evolving state of science on triclosan. EWG also commends the Agency for improving the health risk assessment for children, and for explicit acknowledgement of potential endocrine toxicity of triclosan. Finally, EWG supports the Data Call-In decision by the Agency that would expand the scientific database on environmental and human exposure and health risks of triclosan.

However, significant gaps remain in the EPA's final re-registration eligibility decision for triclosan, including a lack of a cumulative impact assessment for infants and other vulnerable populations and no meaningful consideration of ecological toxicity. With this letter, we outline three main areas on which we strongly recommend EPA to focus its research and regulatory activities before the next re-registration assessment. Specifically, we urge EPA to:

- Comprehensively regulate all sources of triclosan exposure to humans and the environment;
- Fully assess health risks of triclosan to infants, especially breast-feeding infants who may be exposed to this potential endocrine toxicant from multiple sources;
- Conduct a scientifically-valid assessment of environmental exposure, chronic ecotoxicity and long-term effects of triclosan on aquatic life.

Details and rationale for our recommendations are provided below.

1. Comprehensively regulate all sources of triclosan exposure

Regulatory separation between EPA- and FDA-regulated uses of triclosan is the key problem that, if left unaddressed, would continue undermining EPA's efforts to protect the health of humans and the environment from this potent antimicrobial pesticide. No scientific rationale exists that would justify this separation. The current jurisdictional distinction between the two Agencies makes EPA, the primary regulator of triclosan manufacturing, unable to do anything about the widespread triclosan contamination of water and possibly soils and wildlife. As demonstrated by an extensive body of scientific research, triclosan has been linked to hormonal disruption (Ahn 2008; Ishibashi 2004; Kumar 2008; Zorrilla 2008); severe toxicity for algae, foundational producers of oxygen and organic matter in freshwater ecosystems (Orvos 2002; Tatarazako 2004); negative effects on soil microorganisms (Waller 2008); and the potential for development of antimicrobial resistance (Levy 2001). The systemic nature of these environmental and human health dangers can only be addressed with a comprehensive environmental health and safety assessment of triclosan that would not hide behind the artificial separation of triclosan product regulation between FDA and EPA.

EWG research identified triclosan in more than 140 types of consumer products, ranging from HVAC systems and cutting boards to toothbrushes, hand soaps and antiperspirants (EWG 2008a). However, due to lack of ingredient disclosure by manufacturers, consumers are not aware of how frequently they may be exposed to triclosan. Triclosan production is estimated to be between 1 and 10 million pounds per year in the U.S. alone, and nearly 75% of Americans have detectable concentrations of triclosan in their body, indicating daily contact with this chemical (Calafat 2008). In a recent EWG study of cosmetics use by teenage girls, 100% of study participants, young girls aged 14 to 19, had triclosan in their bodies (EWG 2008b). Triclosan has also been detected in breast milk, indicating that a mother exposed to triclosan in personal care products can pass this chemical on to her newborn child (Allmyr 2006). These findings are especially disconcerting in light of the growing body of research that indicates potentially harmful effects of triclosan on the endocrine system (Kumar 2008; Zorrilla 2008).

Household uses such as hand soaps and personal care products are the dominant route of both human exposure and triclosan releases into the ambient environment (Calafat 2008; Heidler 2007; US Department of Health and Human Services 2008). In a recent survey, 76% of 395 commercial soaps examined contained triclosan (Perencevich 2001). EWG cosmetics safety database contains information for 932 different products that include triclosan as an ingredient, including antiperspirant/deodorant; liquid hand soap; facial cleanser; acne treatment; body wash/cleanser; facial moisturizer; toothpaste; body spray; and lipstick (EWG 2008c). And yet, EPA cannot regulate triclosan presence in these types of consumer products because they fall within the FDA jurisdiction. This divided responsibility between two separate government agencies does not serve the public interest since it allows a large percentage of triclosan-containing products to be manufactured and used with no effective health and safety controls.

In order to assure the safety of triclosan for people and the environment and address the outstanding health and safety gaps that still plague the Agency's decision to support re-registration and continued use of triclosan, EPA must assess the cumulative impact of triclosan from both EPA- and FDA-regulated uses. So long as EPA focuses only on EPA-regulated uses of triclosan that are a minority of the overall consumer use and environmental contamination, Agency's assessments would make triclosan exposures appear much safer than a reasonable and thorough risk assessment would conclude.

2. Fully assess health risks of triclosan to infants, especially breast-feeding infants who may be exposed to this potential endocrine toxicant from multiple sources

In considering the health risks of triclosan exposure to infants, EPA chose the 6 to 12 month old age group to represent the high end of exposure of children less then six years old to triclosan-treated products (US EPA 2008a). This step is an improvement from the draft EPA assessment that only considered the risks to the 6-11 year old age group, without accounting for special behaviors and exposure routes that infants may face. In the final assessment, the Agency correctly identified at least four distinct routes by which infants may be exposed to triclosan, including ingestion of triclosan-contaminated breast milk; mouthing of plastic items such as toys, combs and brushes, and playground equipment; hand-to-mouth exposure to residues in dust on children's hands; and inhalation of triclosan-contaminated dust. Additionally, EPA assessment correctly notes that triclosan can enter into the bodies of both children and adults due to normal daily activities such as washing hands with triclosan-containing antibacterial soap; brushing teeth with triclosan-treated toothpaste; exposure to fabrics and textiles such as clothing and sportswear, blankets, mattresses, toothbrush bristles, and other products that may be treated with triclosan; and exposure to triclosan-impregnated polymers and plastics such as food contact surfaces (cutting boards, counter and table tops).

New scientific data now emerging for triclosan indicate that it may disrupt the function of thyroid and reproductive hormones (Ahn 2008; Ishibashi 2004; Kumar 2008; Zorrilla 2008). The finding from animal studies that triclosan can depress serum testosterone levels indicates the potential for long-term effects on the developing fetus and newborns. The developing brain is especially at risk from exposure to toxic industrial chemicals since the blood-brain barrier is not yet fully developed in young children (Grandjean 2006; Stein 2002). Although in the adult brain triclosan levels appear to be low (Siddiqui 1979), for infants who ingest triclosan with breast milk, triclosan circulating in their blood could potentially reach their brain, with so far unassessed health consequences. Despite this well-known biological vulnerability, the current EPA assessment does not specifically address risks to infants younger than 6 months old, an unjustifiable gap that should be urgently addressed by the Agency. A special protection for the health of infants and children from pesticides in food is now upheld as the federal standard under the Food Quality Protection Act of 1996. With the same spirit of care, infants should be protected from exposures to potentially harmful levels of triclosan, whose domestic use, as

assessed by many experts in the area of antimicrobial pesticides, is unnecessary and poses unjustifiable health risks (Aiello 2007; Aiello 2005) (reviewed in (EWG 2008b)).

3. Conduct a scientifically-valid assessment of environmental exposure, chronic ecotoxicity and long-term effects of triclosan on aquatic life

Triclosan is especially toxic to aquatic organisms such as freshwater algae, invertebrates, and fish (US EPA 2008b). Due to wastewater effluent, triclosan contaminates 57.6% of streams sampled by the US Geological Survey scientists; it has been already detected in drinking water sources in ten different states (Focazio 2008; Kolpin 2002). Triclosan-containing domestic cleaners and personal care products are considered by the international research community to be the main source of environmental triclosan contamination (Coogan 2007; Heidler 2007; Xie 2008). A thorough environmental risk assessment, therefore, should take into account triclosan release into the ambient water bodies from municipal wastewater treatment facilities.

The re-registration eligibility decision for triclosan (US EPA 2008b) contains an unacceptable and scientifically unjustifiable inconsistency in approaching human and environmental toxicity risks. When considering human health risk, the Agency conducted an assessment of the aggregate exposure to triclosan from all sources including FDA-regulated uses of triclosan such as hand soaps and toothpaste. In contrast to human health risk assessment, EPA included only a small subset of triclosan-containing consumer products in the ecotoxicity risk assessment. As written in the final decision, the Agency believes that "the antimicrobial uses of triclosan (e.g., triclosan-treated plastic and textile items in households) are unlikely to contribute significant quantities of triclosan into household wastewater and eventually to surface water" (US EPA 2008b). An astute reader will readily notice that the above statement refers exclusively to the uses of triclosan embedded in plastic or textile which are known for fairly limited leaching of triclosan, and entirely omits any mention of the vast majority of household triclosan usage in hand soaps and detergents. On the basis of this extremely narrow subset of products, EPA declared environmental exposures to triclosan safe for aquatic life. This framework change from considering all triclosan products to taking into account EPA-regulated products only is not formally acknowledged in the re-registration eligibility decision, thus creating an illusion of safety that simply is not there.

The first step towards confronting this problem will require EPA to carry out a realistic, science-based risk assessment for water contamination with triclosan from all sources. Below, EWG brings EPA's attention to key scientific results out of dozens of publication that have been omitted from the Agency's assessment of triclosan environmental exposure and ecotoxicity. EWG urges EPA to thoroughly review these studies and incorporate them into a comprehensive environmental risk assessment that is sorely needed.

- As acknowledged by EPA, aquatic organisms are especially at risk from triclosan, both from acute and chronic toxicity (Orvos 2002; Tatarazako 2004; US EPA 2008b). The

EPA risk assessment only accounts for acute triclosan toxicity to aquatic life and states that "chronic aquatic risks are unlikely from consumer uses of triclosan-treated plastic and textile items" (US EPA 2008b). This approach makes no scientific sense: while some amounts of triclosan are removed by wastewater treatment plants, significant quantities are released into the effluent, so that aquatic organisms living downstream are exposed to a constant flow of triclosan (Jackson 2008; Waltman 2006). A risk assessment based on acute toxicity alone would significantly underestimate the overall environmental toxicity of triclosan.

- Triclosan bioaccumulates in algae and snails living downstream of municipal wastewater treatment plants (Coogan 2007; Coogan 2008). In algae, triclosan accumulates at levels up to 1000-2000 times higher compared to surrounding waters (Coogan 2007). In snails, triclosan accumulated to 500-fold levels (Coogan 2008). Triclosan metabolites also bioaccumulate in fish (Balmer 2004). Both the bioaccumulation and the endocrine-disruption potential of triclosan indicate a need for chronic ecotoxicity assessment for this chemical, which, at present, is entirely missing from the EPA re-registration document, invalidating any claims for environmental safety of this compound.
- In wastewater treatment plants, triclosan, a highly hydrophobic molecule, adheres to sludge. According to one recent study, more than 50 % of the triclosan mass entering a wastewater treatment plant remains detectable in sludge, while less than half of the total triclosan mass either biotransformed or degraded (Heidler 2007). So long as large quantities of triclosan are disposed of down the drain, sludge recycling and application of biosolids in agriculture would result in the transfer of this environmental toxicant to the soils (Kinney 2008). Triclosan from biosolids can suppress the function of soil microorganisms, decreasing respiration and nitrification, two key microbiological processes important for soil fertility (Waller 2008). Triclosan-containing biosolids may also contribute to subsequent contamination of surface and ground water with this persistent pollutant. EPA review of triclosan did not consider potential effects of long-term triclosan exposure on agricultural soil fertility and on the health of aquatic life in the vicinity of biosolids application, gaps that need to be remedied in the immediate future.

By conducting an unacceptably narrow exposure estimate for triclosan, choosing to rely only on acute ecotoxicity studies, ignoring the data on chronic ecotoxicity of triclosan, and omitting the most recent scientific research on triclosan effects on aquatic life, the EPA assessment has severely underestimated triclosan risks to the environment. With this woefully insufficient environmental exposure and ecotoxicity assessment, EPA has failed to fulfill its mandate as the *Environmental* Protection Agency. In order to rectify these problems, EWG urges EPA to conduct a comprehensive national survey of triclosan contamination in the environment from all current products and applications and prepare a new risk assessment for triclosan environmental toxicity and hazards to aquatic life based on the effects of chronic exposure.

In conclusion, extensive, unnecessary indoor use of triclosan-containing products and resultant water contamination with triclosan pose potential health risks to humans, animals, and plants and increase the chances of breeding antimicrobial resistance. When it comes to the mother whose child may be exposed to triclosan in both breast milk and tap water or to the contaminated algae and fish that live downstream of urban wastewater effluent, triclosan contamination is an environmental health concern that urgently needs to be addressed. EPA should take leadership in scientifically-based, health-protective regulation of triclosan and ensure that appropriate risk mitigation steps are taken to protect all vulnerable human and ecological populations from a chemical for which the majority of uses are considered to be non-essential.

EWG looks forward to working with the Agency on these important areas and we will be happy to provide our feedback and comments as EPA continues to assess human and environmental toxicity data for triclosan. We are certain that with concerted effort and involvement of multiple stakeholders, many of the present risks of triclosan would be avoided and better health protection implemented, while preserving the use of this potent antimicrobial pesticide in medical settings where it is truly needed.

With best regards,

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