April 8, 2011

Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P)
Environmental Protection Agency
1200 Pennsylvania Ave., NW.
Washington, DC 20460-0001

Re: Petition for a Ban on Triclosan [EPA–HQ–OPP–2010–0548; FRL–8852–8]

To Whom It May Concern:

Environmental Working Group (EWG) is a non-profit public health and environmental research and advocacy organization based in Washington, DC. We work to combat the health risks from chemical contamination of food, water, consumer products and the environment. As a co-signer to the 2010 Citizen Petition for a Ban on Triclosan, EWG strongly supports a suspension of non-medical uses of triclosan while EPA reexamines the safety of currently registered uses. We are particularly concerned that EPA has not comprehensively assessed the safety of cumulative exposures of triclosan for the developing fetus, infant and child.

Triclosan has been used for 40 years as an antimicrobial ingredient in consumer and commercial products. Despite widespread concerns about the chemical's toxicity—the fact that the chemical is detected in the majority of Americans, and its potential to harm aquatic life and form toxic byproducts in water or the environment—there are few restrictions on its use. The American Medical Association does not recommend use of antimicrobial products in the home (Tan 2002), stating: "No data support the efficacy or necessity of antimicrobial agents in such products, and a growing number of studies suggest increasing acquired bacterial resistance to them." According to a Food and Drug Administration Nonprescription Drugs Advisory Committee, triclosan soaps are no better than plain soap and water for preventing the spread of infections or reducing bacteria on the skin (FDA 2005).

EWG research finds that:

- **A wide range of home products contain triclosan and contribute to exposures.** EWG research shows that with no assessment of health risks to infants, regulators have approved triclosan for use in 140 different types of consumer products including liquid hand soap, toothpaste, undergarments and children's toys (EWG 2008). This exposure has been allowed despite the fact that the chemical ends up in mothers' breast milk and poses potential toxicity to fetal and childhood development.
- **Triclosan commonly contaminates the human body.** EWG biomonitoring research has found triclosan in 42 of the 49 participants tested, including all 20 adolescent girls (EWG 2008).

Triclosan is a widely used antimicrobial pesticide, present in everything from clothing, food preparation products and personal care products to the plastics making up any number of consumer goods. Its over-use threatens to breed microbial resistance, including cross-

resistance to other antibiotic chemicals, potentially making triclosan and other important antibacterial chemicals less effective for the applications where they are medically effective and appropriate (EU SCCP 2010). In 2008, EWG tallied 140 different types of triclosan containing items. DailyMed, a service of the National Institutes of Health, lists 95 brands of liquid soap with triclosan as an active ingredient (Daily Med 2011).

The European Commission's Scientific Committee on Consumer Products ruled in June 2010 that triclosan uses should be restricted to reduce the potential for resistance, and called for use to be limited to applications "where a health benefit can be demonstrated" (EU SCCP 2010). In fact, the FDA has determined that "antibacterial" soaps, one of the predominant uses of triclosan, are no better than regular soap and water at killing germs and reducing the spread of infection (FDA 2005).

Triclosan producers vigorously defend the use of their chemical. Nevertheless major manufacturers are removing triclosan from some products. In 2010, Colgate Palmolive removed triclosan from its "ultra-Palmolive Antibacterial" dish soap and in its Softsoap brand hand soaps. The company now uses Lactic acid as the antibacterial additive. Its toothpaste, sold under the "Colgate Total" brand, still contains the chemical.

We believe that EPA and FDA must limit triclosan to critical public health uses, and restrict the use of this antimicrobial ingredient in consumer and commercial goods for which there is no proven health benefit tied to its inclusion.

In addition to toxicity and exposure concerns raised in the 2010 petition, we would like EPA to consider new evidence of triclosan exposure or toxicity:

- **Triclosan is found in nearly all Americans, including vulnerable subgroups**. A recent analysis of CDC's NHANES data finds that triclosan levels in Americans increased dramatically between 2003-04 and 2005-06 (CDC 2010). Increases were noted in each age group and race/ethnicity. Overall, triclosan levels were 40 to 50 percent higher in the second 2-year period. Other biomonitoring data reveal triclosan in sensitive groups, including detectable levels in 100 percent of teenage girls in EWG testing (EWG 2008), 87 percent of pregnant women participating in NHANES (Woodruff 2011), in the breast milk of each of 36 Swedish mothers tested (Allmyr 2006) and in one-fifth of infants in neonatal intensive care units (Calafat 2009). EPA must explore the intensity and potential risks of triclosan exposures for the developing fetus, breastfed infant and other sensitive groups.

- **The use of triclosan-containing personal care items results in intense human exposures**. Allmyr et al. (2009) found an approximate 200-fold increase in plasma triclosan concentrations for 14 participants after they had use triclosan-containing toothpaste for 2 weeks. While the study did not find significant changes in CYP3A4 induction or thyroid measurements resulting from triclosan elevations, other potential toxicological impacts of triclosan exposures must be studied.

In addition to direct contact with triclosan-containing items, the chemical is detected in household dust samples at concentrations of around 400 parts per billion (Fan 2010). Household dust is a clear route of ingestion for young children who place their hands and non-food objects in their mouths.

- **Children with greater triclosan exposure report increased diagnosis of allergies and hayfever**. In an analysis of CDC's NHANES data for triclosan and bisphenol A, University of Michigan researchers found that triclosan was positively associated with diagnosis of allergies and hayfever in 678 study participants age 6 to 18 years old (Clayton 2010).

- **There is mounting evidence of potential antibiotic resistance and cross-resistance by harmful bacteria**. Despite European recommendations to use triclosan judiciously to reduce the risk of bacterial resistance, the U.S. EPA and other federal agencies have done little to monitor and assess the potential for triclosan uses to have an overall negative effect on public health. In a September 2010 publication, researchers reported 4 percent triclosan resistance in 400 animal and human isolates of *Salmonella*. More than half of all isolates with triclosan resistance were resistant to multiple antibiotics, leading the researchers to conclude that "a reservoir of strains with low-level decreased triclosan susceptibility is present in animals and humans. These isolates are MDR [multidrug-resistant] as a result of generic mechanisms of antimicrobial resistance" (Copitch 2010).

- **Triclosan use in consumer products contaminates the ambient environment.** Triclosan is toxic to aquatic ecosystems. Decades of use have lead to widespread environmental contamination of the aquatic environment, typically through release of treated wastewater into streams and rivers. In its risk assessment, EPA reported that at the highest concentrations of triclosan found in U.S. streams, there is potential for acute risks to freshwater algal species (EPA 2008). Due to its toxicity towards a wide spectrum of microbial and algal species, triclosan may disrupt critical ecological processes performed by beneficial microorganisms in nature (Lawrence 2009, Miller 2008, Neumegen 2005, Waller 2009). In addition, triclosan bioaccumulates in algae, snails, fish and amphibians that live downstream from wastewater plants, frequently at concentrations several orders of magnitude above ambient levels (Balmer 2004, Coogan 2007, Palenske 2010).

  Contaminated stream and river sediments may also serve as a reservoir of triclosan that would adversely impact bottom-dwelling organisms in particular (Binelli 2009, Miller 2008). During the early, most sensitive stage of their life cycle, bottom-feeders may be exposed to levels of triclosan that have been associated with embryonic toxicity, anatomic changes, and developmental delays (Oliveira 2009, Palenske 2010).

  Triclosan enters the land environment through application of sewage sludge from wastewater treatment plants on agricultural lands (Cha 2009). Wu (2011) found that triclosan concentrated in the roots and beans of soybean plants grown in soil that had been treated with sewage sludge. On land, triclosan has been shown to inhibit soil

respiration and nitrification processes that are essential for preserving soil fertility (Waller 2009).

Triclosan can form more toxic compounds after its release into the natural world. A highly toxic metabolite of triclosan, methyl triclosan has been detected in carp downstream from Las Vegas (Leiker 2009). EPA did not consider the potential environmental effects of this metabolite in its triclosan risk assessment. Likewise, environmental effects of known triclosan degradates including chloroform and a form of dioxin were not included in the risk assessment.

We urge the Agency to halt triclosan use in products for which this chemical is not essential, and assure that the remaining registered uses do not collectively risk harm via direct human toxicity, environmental damages or reduced efficacy of antibiotics for health-critical uses.

Sincerely,

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