

## Triclosan-containing antibacterial soaps neither safe nor effective:

### Comments from Environmental Working Group on the Food and Drug Administration proposed data requirements for antibacterial soaps

June 16, 2014

Re: Safety and Effectiveness of Consumer Antiseptics; Docket No. FDA-1975-N-0012

Environmental Working Group is a non-profit public health research and advocacy organization based in Washington, DC that has been raising concerns about antibacterial agents for many years. With this letter we express strong support for the FDA's proposal to evaluate the safety and efficacy of consumer antibacterials soaps.

In December 2013, the FDA announced that antibacterial soaps with ingredients such as triclosan and triclocarban might be neither safe nor any more effective than plain soap and water, stating: "*The record does not currently contain sufficient data to show that there is any additional benefit from the use of consumer antiseptic hand or body washes compared to nonantibacterial soap and water*" (FDA 2013).

Despite the absence of efficacy data, manufacturers have aggressively marketed antibacterial soaps to the American public. As a result of widespread use of such soaps, 75 percent of Americans have triclosan in their bodies, according to the National Health and Nutrition Examination Survey data (Calafat 2008). Triclosan has been found in pregnant women (Woodruff 2011), in cord blood (TNO 2005) and in breast milk (Dayan 2007), indicating that triclosan exposures start from the first moments of life. A pilot study found triclocarban in a third of urine samples collected from American adults with no known triclocarban exposure (Zhou 2012). The exposures would likely be much higher among consumers who buy triclocarban products.

New data point to the risks of triclosan and triclocarban to human health due to their endocrine-disrupting potential, indicating that *each and every non-medical use* of these potent chemicals must be scrutinized from public health and safety point of view.

**EWG fully supports the FDA's proposal to assess the safety and efficacy of antibacterial soaps. This step is long overdue and should be made without delay in order to protect public health.**

**EWG also urges the Agency to go further and review all uses of antibacterial ingredients triclosan and triclocarban in products under the FDA oversight. For improving the current proposal, EWG recommends for the FDA to:**

- Require a detailed health and safety evaluation for ingredients in daily-use consumer products before they are allowed on the market;
- Examine all uses of antibacterial ingredients, not just in antimicrobial soaps but in all personal care products.

Details and the rationale for our recommendations are provided below.

## **1. The FDA should require detailed health and safety evaluation for ingredients in daily-use consumer products before they are allowed on the market.**

EWG has long advocated for safety oversight of ingredients in cosmetics and personal care products before they are allowed on the market. For personal care product ingredients that are already on the market, health and safety data must be collected and made available both to the FDA and to the general public without delay. The urgency and scrutiny should be particularly high for personal care product ingredients that have been found in people by biomonitoring studies. Triclosan and triclocarban are examples of such high-priority chemicals – they are found in human body and they have a potential to negatively impact human health.

*As a group that since 2007 has called on the government agencies and personal care product manufacturers to limit the use of products containing triclosan and triclocarban and a co-signer to the 2010 Citizen Petition for a Ban on Triclosan, EWG whole-heartedly supports the FDA's efforts to assess the safety and efficacy of antibacterial soaps (EWG 2007; EWG 2008a; EWG 2011; EWG 2014a). EWG also urges the FDA to go further and apply the lessons learned from triclosan and triclocarban soaps to all personal care products under the FDA oversight.*

The studies conducted over the past decade show that triclosan and triclocarban can cross the human skin and remain in the body, even when these products are used for a few seconds or minutes during a hand wash or a shower. Data from the National Health and Nutrition Examination Survey 2003-2004 show that 75 percent of Americans have triclosan in their urine samples; triclosan concentrations were highest among the 20-to-29 age group (Calafat 2008). EWG biomonitoring research found triclosan in 42 of the 49 participants tested, including all 20 adolescent girls who took part in the study (EWG 2008b).

Recent research demonstrates that triclosan has effects on the thyroid, estrogen, and testosterone hormones in laboratory animals, including mammals (Chen 2008; Koeppel 2013; Stoker 2010; Zorrilla 2009). While data for triclocarban are still limited, studies have suggested that it also might have hormone-disrupting potential (Ahn 2008; Chen 2008).

Daily use of antibacterial soaps could have potential long-term adverse effects on human health, as the FDA acknowledges (FDA 2013). Of greatest concern is the fact that even today, decades after triclosan and triclocarban were put into mass production, neither antibacterial soap manufacturers nor government agencies have conducted any long-term animal studies to address the consequences of hormonal effects of these potent chemicals on growth and development, especially for the vulnerable stages of brain development, sexual differentiation and fertility.

The FDA wrote in its announcement that “A hormonally active compound that causes reproductive system disruption in the fetus or infant may have effects that are not apparent until many years after initial exposure. There are also critical times in fetal development when a change in hormonal balance that would not cause any lasting effect in an adult could cause a permanent developmental abnormality in a child” (FDA 2013). *EWG entirely agrees with the FDA position on the hormonal risks of antibacterial soaps.* Data from animal studies suggest that the risks of triclosan exposure are likely higher for young children and adolescents compared to adults. For example, triclosan exposure significantly decreased thyroid hormone T3 and T4 concentrations in the male juvenile rats (Zorrilla 2008). In young female rats, triclosan affected estrogen-mediated responses and suppressed thyroid hormone T4 (Stoker 2010).

Changes in thyroid hormones were also observed in a cross-sectional analysis of data on urinary biomarkers of triclosan exposure and serum thyroid measures obtained as part of the 2007–2008 National Health and Nutrition Examination Survey (NHANES) (Koepper 2013). Another study based on the NHANES data found that higher levels of urinary triclosan were associated with greater body mass index (Lankester 2013). The study authors hypothesizes that triclosan could increase the body weight by interfering with the thyroid hormone function and by changing the gut flora composition (Lankester 2013).

The limited human epidemiological data currently available have not yet addressed the question of possible thyroid and reproductive hormone changes in young children exposed to triclosan and triclocarban. Yet, this risk must be considered in a decision on the safety of antibacterial soaps for daily consumer use. So far, neither the FDA nor the EPA has comprehensively assessed the safety of cumulative exposures of triclosan for the developing fetus, infant and child. Such a comprehensive assessment is urgently needed, as EWG pointed out in our 2011 letter supporting the Citizen Petition for a Ban on Triclosan (EWG 2011).

*In sum, EWG expresses complete support for the FDA's proposal to require detailed safety data for ingredients in antibacterial soaps. EWG also urges the FDA to go one step further and require health and safety evaluation for ingredients in daily-use consumer products before they are allowed on the market. Waiting for decades before issuing the data requirement, as has been the case for consumer antibacterial soaps, does not serve public health. The FDA needs to be more pro-active in protecting consumers from products with poorly tested ingredients that might cause potentially serious long-term adverse health effects.*

## **2. The FDA needs to go a step further and address all uses of antibacterial ingredients in personal care products.**

Antibacterial soaps have been sold since 1970s without proof that these soaps are worth the money spent on them. And the cost to the consumer is significant: annual U.S. sales of disinfectant and antibacterial products exceed a billion dollars (Smith 2013). The antibacterial soap experiment has been rolled out on a grand scale: according to EPA, both triclosan and triclocarban are High Production Volume Chemicals, with annual production reaching or exceeding million pounds (EPA 2002; EPA 2006).

Consumer antibacterial soaps with triclosan and triclocarban were put on the market without data demonstrating clinically significant health benefits from their use in a non-hospital setting (Aiello 2007). EWG believes that this fact represents a failure of the FDA oversight of the personal care product market. *All of the safety and efficacy studies that the FDA is now proposing for triclosan, triclocarban and other antibacterials should have been conducted before these products were put on the market.* Products without a full safety dossier should not be advertised and sold to consumers under the “good for your health” guise.

Studies show that consumer use of antibacterial soaps does not decrease the infection rates, so that the incidence of disease is the same between the users of ordinary soap and antibacterial soap (Larson 2004; Luby 2005). The FDA is now proposing that the use of antiseptic ingredients in consumer antibacterial soaps be supported by studies that demonstrate a direct clinical benefit such as a reduction of infections, which is a common-sense requirement given that consumers buy such products to protect their health.

EWG fully supports the FDA proposal to call for efficacy data on antibacterial soaps and finds that such an approach would be consistent with recommendations of national and international expert bodies on the issue. For example, the European Union Scientific Committee on Consumer Safety called for triclosan use to be limited to applications “where a health benefit can be demonstrated” (EU SCCP 2010). Similarly, the United Kingdom Hygienist Panel stated: “the addition of triclosan to a product must be substantiated in any claim of preventive or therapeutic health benefit” (Leaper 2011). The FDA’s Nonprescription Drugs Advisory Committee has delivered the same message to the Agency nine years ago (NDAC 2005).

Over-use of antibacterial soaps in settings where they do not provide any health benefit is of particular concern because of a risk of bacterial resistance development, as pointed out by multiple research reports and expert panel assessments (Aiello 2007; EU SCCP 2010; NDAC 2005; Tan 2002). Bacterial resistance to triclosan has been already observed in laboratory setting (Copitch 2010). If the long-term use of antibacterial soaps were to contribute to the growing problem of microbial resistance or weaken the body’s ability to defend itself from pathogens, this could lead to potential clinical harm.

Most bacterial resistance cases in the United States today are due to excessive use of medical-grade antibiotics, especially in livestock (CDC 2014). The problem is significant: the Centers for Disease Control and Prevention statistics show that in the United States, more than two million people are sickened every year with antibiotic-resistant infections, with at least 23,000 dying as a result (CDC 2013). Different government agencies, including the FDA itself, are proposing steps to combat this problem (FDA 2014).

Recent studies suggested that, because the mode of action of antimicrobials such as triclosan is similar to antibiotics, bacteria that become resistant to antimicrobials could also become resistant to medical-grade antibiotics (Ortega Morente 2013; Poole 2002). Over-use of triclosan could cause development of cross-resistance to antibiotics, which would make treatment of life-threatening infections with antibiotic-resistant bacteria even more difficult (Alliance for the Prudent Use of Antibiotics 2011; White and McDermott 2001).

Latest data suggest that potential spread of infections due to triclosan use is not just a hypothetical concern. A study published in March 2014 reported that triclosan could be detected in nasal secretions of healthy human adults and that the presence of triclosan correlated with the nasal colonization by opportunistic pathogen *Staphylococcus aureus*, a risk factor for several infections (Syed 2014). The study reported that triclosan-exposed rats were more susceptible to *S. aureus* colonization compared to rats not exposed to triclosan (Syed 2014).

New data also find a link between extensive use of triclosan and allergy and asthma problems among children. In an analysis of the 2003-2006 NHANES data for triclosan and bisphenol A, University of Michigan researchers found that higher triclosan levels were associated with more common diagnosis of allergies and hay fever among 6-to-18-years-old (Clayton 2011). In an analysis of the 2005-2006 NHANES data, the Johns Hopkins University researchers found that higher triclosan levels were associated with more frequent sensitivity to respiratory and food allergens among the same age group (Savage 2012). A study in a laboratory mouse model of asthma found that one month of skin exposure to triclosan worsens respiratory allergy symptoms, increasing both allergen-specific and nonspecific airway hyperreactivity (Anderson 2013).

A publication from February 2014 suggested that triclosan could exacerbate asthma (Savage 2014). Analyzing NHANES 2005-2010 data for 639 study participants who reported both triclosan use and diagnosis with asthma, Harvard University researchers found that the likelihood of reporting an asthma attack increased with increasing urinary triclosan levels (Savage 2014).

Latest studies summarized above underscore the risks of triclosan and suggest that antibacterial soaps could bring in previously unanticipated health risks. Therefore, avoiding all sources of unnecessary exposure to antibacterial chemicals would protect public and individual health. Yet, triclosan and triclocarban are found not just in antibacterial soaps, they are also used in many types of personal care products. Even consumers who know about the risks of antibacterial soaps and choose to avoid them could be unknowingly exposed to these chemicals from other products that might not advertise their antibacterial ingredients on the front label.

*EWG calls on the FDA to assess the uses of triclosan and triclocarban not just in antibacterial soaps but in all products under the FDA oversight where these ingredients could be used.*

As of May 2014, EWG analysis found that triclosan was present in 30 antiperspirant and deodorant products, 19 toothpaste and teeth whitening products, 17 body and face washes, 10 eye shadows as well as blushes, moisturizers and other personal care products. Triclocarban, an antibacterial ingredient in bar soaps, was found in 8 antiperspirants/deodorants. These data are drawn from EWG's Skin Deep personal care product ingredient database and correspond to product formulations collected in the last three years (EWG 2014b). While the product formulations on the market change constantly and the EWG database does not include every product on the market, the available data represent a snapshot of the U.S. market and indicate that manufacturers add antibacterial ingredients to a variety of personal care products.

Further, although the FDA proposal has not considered environmental fate of antimicrobials such as triclosan and triclocarban, this factor must be included in a comprehensive assessment for these chemicals. Triclosan and triclocarban from antibacterial soaps and personal care products end up in wastewater treatment plants and sewage sludge (EWG 2007; Halden 2014). When sewage sludge is applied on agricultural fields, food crops can pick up and accumulate triclosan and triclocarban (Cha 2009; Mathews 2014). From wastewater treatment plants, triclosan and triclocarban end up in water bodies across the United States that could serve as sources of drinking water (Halden and Paull 2005). In a 1999-2000 nationwide reconnaissance, the U.S. Geological Survey found triclosan in 57 percent of the 139 U.S. waterways in agricultural or urban watersheds (Kolpin 2002). Food and water represent a new, little understood route of exposure to antibacterial soap ingredients that have become ubiquitous in the human environment.

*A comprehensive assessment of human exposure to antibacterial chemicals must consider both direct and indirect routes, including consumer use of antibacterial soaps and other personal care products; soaps used in institutional and professional settings such as schools and offices where soap dispensers are not labeled with ingredient information; indirect exposure from contaminated food and water; and contact exposure from numerous consumer products with embedded antibacterial ingredients such as kitchen cutting boards, some types of clothing, toys and many other products (EWG 2008a).*

Antibacterial chemicals have a great utility in the hospital and medical settings. In daily consumer use they are, as researchers have pointed out for a long time, "just risky" (Aiello 2007).

## **Conclusion**

As described in this letter, EWG strongly supports the FDA's plan to require safety and efficacy data for antibacterial soap ingredients, a proposal that is long overdue. EWG also urges the FDA to apply the lessons learned from triclosan and triclocarban to ingredients in other products under the FDA's oversight.

The FDA request for data on triclosan, triclocarban and other antibacterial ingredients should not be limited to antibacterial soaps only but should apply to all personal care products that contain triclosan and triclocarban. Allowing untested products on the market does not serve the interests of public health and contradicts the FDA's mission to protect the consumers.

The FDA must require a detailed health and safety evaluation for ingredients in daily-use consumer products before they are sold. For ingredients that are already on the market, health and safety data must be collected and made available both to the FDA and to the general public without delay. Without such data, the FDA cannot ensure that products in the marketplace are safe for the general public and especially for vulnerable populations such as children.

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