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November 16, 2010

The Honorable Margaret Hamburg  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Hamburg:

Antibiotic resistance and contaminated water have created a public health crisis in the United States. The scientific community – including prominent medical journals and government agencies – concur that routine usage of medically-important antimicrobials in over-the-counter consumer products is a significant contributor to these problems. As you conduct your review of triclosan in consumer products, we respectfully request you to consider the full weight of scientific evidence regarding this antibacterial chemical.

Most consumer products containing triclosan are no more effective in protecting against illness than products that do not. Furthermore, scientific studies have shown that triclosan has been detected in surface water and may damage the human endocrine system. Other studies in bacteria have raised the possibility that triclosan contributes to antibiotic resistance. A recent study by the Alliance for the Prudent Use of Antibiotics (APUA) and Cook County Hospital found that antibiotic-resistant bacteria generated \$16.6 to \$26 billion dollars per year in extra costs to the U.S. health care system.

Recent increases in the use of triclosan have raised concerns about its possible environmental effects, as well as potential effects on human health. Indeed, recent scientific studies found triclosan present in 57 percent of sampled U.S. streams thought to be susceptible to agriculture or urban activities in 30 states. When exposed to sunlight under certain conditions, triclosan may be transformed into the known carcinogens dioxin and chloroform. In addition, triclosan can be highly toxic to different types of algae, thereby damaging specific organisms as well as potential destruction of larger ecosystem balance.

While triclosan is regulated by two different federal agencies, the Food and Drug Administration (FDA) oversees its use in personal-care products, medical devices and products that come into contact with food. Triclosan is found in a growing number of products regulated by FDA including liquid soaps, hand sanitizers, dishwashing liquids, shaving gels and even socks, workout clothes and toys. In a letter to Representative Ed Markey dated February 23, 2010, FDA stated that recent research raises “concerns” about the possible health effects of triclosan. The FDA confirmed that recent scientific studies raise questions about whether triclosan disrupts the body’s endocrine system and whether it results in antibiotic resistant bacteria.

Earlier this year, in its response to another inquiry by Representative Markey, the Environmental Protection Agency (EPA) noted that a review of triclosan under the Endocrine Disruptor Screening Program (EDSP) provided evidence of its endocrine disrupting potential. Triclosan is clearly a threat to our health. The precedent for this conclusion is clear:

- The presence of triclosan in the human body (as evidenced by scientific studies of its activity in blood, urine and breast milk) imposes a dangerous “body burden.”
- Bacterial resistance to antibiotic medications and antibacterial cleansers is just one category of threats emanating from the growing body burden of triclosan. Such resistance renders humans, especially vulnerable subpopulations, wide open to bacteria-induced illnesses and death.
- Endocrine disruption is another potential result of triclosan bioaccumulation in the body. This effect, in turn, poses serious threats to thyroid and other organ functions, and it can also influence the development of cancer.
- Wastewater contamination by triclosan is a serious health threat. Triclosan products used in the home and in the workplace yield residues that enter wastewater from rinsing, cleaning, and other normal activities. Because these residues are not rendered harmless by the wastewater treatment process, they are free to reenter the environment—and ultimately the human body.
- Once in the larger environment, triclosan poses numerous additional dangers including the threat of cancer development and contributing to the destruction of ecological balance.
- Finally, numerous scientific studies and reports indicate that triclosan is no more effective than soap and water. In 2005, an advisory panel to the FDA stated that there was no evidence that antibacterial soaps work better than regular soap and water.

Food & Water Watch and Beyond Pesticides, on behalf of 30 other consumer protection and environmental groups, submitted an Amended Citizens Petition for a Ban on Triclosan to FDA on July 15, 2009. This was their second petition to the agency. However, FDA has yet to respond to petitioners regarding these concerns. We understand that FDA will respond to the citizens’ petition at the end of the review and we look forward to that response. Moreover, FDA has not finalized the monograph that governs topical antiseptics including soaps, and has not announced plans to address the use of triclosan in cosmetics or other products. We request information regarding the status of the “Amended Citizens Petition for a Ban on Triclosan.” In addition, we encourage FDA to finalize the monograph governing topical antiseptics.

FDA’s review of triclosan must be submitted to Congress in April of 2011. We urge FDA to consider the full weight of scientific evidence leading to this simple conclusion: Triclosan should

be banned in consumer and personal care products. It is of the utmost importance to protect the public health of citizens adversely affected by triclosan usage and to protect our environment.

We appreciate the Obama Administration's willingness to reevaluate the possible health impacts of chemicals that have been in widespread use among the American public. We look forward to your response.

Sincerely,



Louise M. Slaughter  
Member of Congress



Betty McCollum  
Member of Congress



Raúl M. Grijalva  
Member of Congress