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December 22, 2010

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

Dear Commissioner Hamburg:

I write to request an update on FDA's efforts to finalize its regulations for over the counter (OTC) topical antiseptic drug products, including consumer soaps and hand sanitizers, which often contain two ineffective and potentially harmful chemicals known as triclosan and triclocarban. In the thirty-five years since FDA first began to develop these regulations, data has been mounting that indicates that these chemicals are endocrine-disruptors capable of interfering with hormones critical for normal development and reproduction, and that additionally, their widespread use could be contributing to the development of antibiotic-resistant strains of bacteria. Moreover, there is no evidence that the use of triclosan and triclocarban in antibacterial soaps and washes provides any benefit over washing with regular soap and water.[1] Alarmingly, the most recent data released in July 2010 by the Centers for Disease Control and Prevention (CDC) shows that there was an increase of 42% in the amount of triclosan found in Americans in 2005-2006 versus data collected in 2003-2004.

Since these chemicals are used in a range of products including consumer soaps and hand sanitizers without being bound by FDA regulations that have thus far taken more than 3 decades to craft, in April 2010, I wrote letters to thirteen companies that manufacture consumer soaps and hand washes, products that are intended to come into contact with food, and products that are marketed to children asking them to voluntarily cease using triclosan and triclocarban in these product categories; however most companies refused to take any action to eliminate these chemicals, and instead said that they would await FDA action and change practices only if required by law or regulations.

[1] http://www.fda.gov/forconsumers/consumerupdates/ucm205999.htm

As indicated in FDA's February 2010 letter to me[2], the scientific literature has extensively linked triclosan and triclocarban to endocrine disrupting effects, with the ability to interfere with male and female reproductive hormones as well as the ability to alter thyroid function. Although triclosan was originally introduced in the healthcare setting as a surgical scrub, over the last decade there has been a rapid increase in the use of both triclosan and a related compound triclocarban, in a number of consumer products including soaps, handwashes, shave gels, cosmetics, kitchenware, clothes and toys. By FDA's own estimation the "majority of consumer antibacterial soaps contain triclosan or triclocarban as active ingredients[3]." A physician-performed survey published in 2001 found that 76% of liquid and 29% of bar soaps (plain and antibacterial) contain one of these two chemicals.[4] A decade later, if this survey were performed again it would be expected that the prevalence of triclosan and triclocarban in consumer soaps would be much greater given the proliferation of antibacterial soaps on the market. Despite their widespread use, in April 2010, [5] FDA reiterated its 2005 position[6] that there is no evidence that triclosan in antibacterial soaps is superior to washing with plain soap and water for reducing transmission of or preventing infection for consumers. FDA also stated that it believed that existing data on the ability of triclosan and triclocarban to interfere with the body's normal hormonal functioning "raise valid concerns about the [health] effects of repetitive daily human exposure to these antiseptic ingredients."

The FDA's rulemaking – called a monograph – which was first drafted in 1972, would establish conditions and labeling requirements under which over-the-counter (OTC) topical antiseptic drug products (including consumer products that contain antibacterial ingredients such as triclosan) would be safe and effective. It has been over 35 years since a draft of this rule was published in the Federal Register and although the proposal has been revised several times, it has never been finalized. In this void, numerous scientific studies were published that raised concerns about the human health risks and effectiveness of triclosan and triclocarban, two common ingredients used in hand soaps and sanitizers. As a result of FDA's failure to act to finalize this rule, chemicals such as these can be widely used despite substantial scientific data that question their safety.

Since my last letter to you on this subject in January 2010, there have been several scientific studies that have updated our understanding of the health impacts, exposure and environmental distribution of triclosan and triclocarban. For example, in July the CDC released updated bio-monitoring information that compared human concentrations of triclosan in 2005-2006 to what was found previously in 2003-2004[7], when triclosan was found in 75% of all

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[2] http://markey.house.gov/docs/fdatriclosanresponsereduced.pdf
[3] http://markey.house.gov/docs/fdatriclosanresponsereduced.pdf
[4] Perencevich EN, Wong MT, Harris AD. 2001. *National and regional assessment of the antibacterial soap market: A step toward determining the impact of prevalent antibacterial soaps.* Am J Infect Control, 29(5):281-3.
[5] http://www.fda.gov/forconsumers/consumerupdates/ucm205999.htm
[6] http://www.webmd.com/news/20051020/fda-panel-no-advantage-to-antibacterial-soap
[7] http://www.cdc.gov/exposurereport

Americans.[8] Based on the most comprehensive data available on chemical exposure, the CDC found that the concentration of triclosan in the urine of Americans has increased by an average of 42 % in all age groups, both genders and all reported ethnicities[9]. When looking only at children ages 6-11, the increase is over 55 %. While data on more recent exposure levels has not been released, one could reasonably assume that the concentration of triclosan in the human body and the prevalence of triclosan in the population has also continued to increase as the number of consumer products that contain this chemical also increased, and as concerns about the transmission of H1N1 or other flu strains mount each flu season.

Furthermore, data indicates that additional exposure to triclosan and triclocarban may be occurring through consumption of contaminated food and water. A Johns Hopkins Bloomberg School of Public Health study found that about 75 percent of triclosan makes it through water treatment methods, ending up in surface water and municipal sludge, which is commonly applied to agricultural crops as a fertilizer.[10] Triclosan has also been found in 60 percent of U.S. streams according to a U.S. Geological Survey conducted between 1999 and 2000.[11] Additionally, a study published earlier this year[12] indicates the ability of plant crops to uptake triclosan and triclocarban, that could be present in irrigation water or fertilizer, concentrating these toxic compounds in their roots, leaves and beans, which are routinely harvested for food.

In light of the potential health and environmental damage caused by these chemicals and doubts about their efficacy, several countries, including the European Union have taken action to ban or restrict the use of triclosan in many consumer products, including those that would come into contact with food. Given FDA's inaction on this issue I wrote letters to thirteen companies known to make and market U.S. products that contain triclosan or triclocarban asking them to voluntarily remove these chemicals from products that will come into contact with food, consumer soaps (where FDA has found them to be relatively ineffective) and products marketed specifically for children. To their credit, several of the companies responded noting changes to a triclosan-free production process.

- Acme United Corporation – the maker of Clauss knives began to shift all products away from triclosan in the summer of 2009, following a decision by the manufacturer of triclosan to withdraw its application for use as a food contact additive in the European

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[8] Calafat AM, Ye X, Wong LY, Reidy JA, Needham LL. 2008. *Urinary concentrations of triclosan in the U.S. population: 2003-2004*. Environ Health Perspect,116(3):303-7.
[9] http://www.cdc.gov/exposurereport/pdf/Update_Tables.pdf
[10] Heidler J, Sapkota A, Halden RU, 2006. *Partitioning, Persistence, and Accumulation in Digested Sludge of the Topical Antiseptic Triclocarban during Wastewater Treatment.* Environmental Science and Technology, 40(11):3634-9.
[11] Rolf U. Halden and Daniel H. Paull. 2005. *Co-Occurrence of Triclocarban and Triclosan in U.S. Water Resources*. Environmental Science and Technology, 39(6):1420–1426.
[12] Wu C, Spongberg AL, Witter JD, Fang M, Czajkowski KP. 2010. *Uptake of Pharmaceutical and Personal Care Products by Soybean Plants from Soils Applied with Biosolids and Irrigated with Contaminated Water.* Environ. Sci. Technol., 44 (16), 6157–6161

Union. The company anticipates that all products, including pencil sharpeners, rulers and scissors will be shifted to non-triclosan ingredients globally by the end of this year.

- Victorinox – the manufacturer of Swiss Army knives removed triclosan from its catalog of products where it was previously used to treat the handles of a line of cutlery. Several months ago, the company ceased making this line of cutlery and has no plans to resume sales of this product line– it was noted that these decisions were based on market and economic considerations.
- Reckitt Benckiser – the producer of several consumer face washes and hand soaps is currently reformulating its remaining U.S. products that contain triclosan into alternative triclosan-free formulas to be completed by 2011. The company does maintain one professional hand soap formulation that contains triclosan and stressed that this product is sold only to institutional customers and is not meant for consumer use.
- Colgate-Palmolive – the company responsible for a host of dishwashing, body and hand soaps among other consumer products, indicated that Softsoap® Antibacterial Handsoap is the only Colgate-Palmolive consumer soap or shower gel product line sold in the U.S. that contains triclosan. The company noted that it plans to soon introduce a new antibacterial dishwashing formula without triclosan to replace the current Palmolive antibacterial dishwashing product on the market.

The remaining companies[13] largely referenced the FDA's regulatory inaction as evidence that FDA was supportive of the safety and effectiveness of triclosan, and indicated that they had no intention of changing their corporate practices or formulations without sufficient guidance by the FDA – emphasizing the need for FDA to rapidly act to finalize regulations that govern the use of triclosan and triclocarban in consumer products.

I request that you provide a full and complete response that details the actions that FDA has taken in the last 12 months to finalize its regulations on OTC products and the use triclosan and triclocarban, and provide a detailed timeline regarding your efforts to finalize these long-overdue regulations. Please provide this response no later than January 12, 2010. Should you have any questions about this request, please have your staff contact Dr. Avenel Joseph of my staff or Dr. Michal Freedhoff of the Energy and Environment Subcommittee staff at (202) 225-2836.

Sincerely,

Edward J. Markey
Chairman
Subcommittee on Energy and Environment

[13] One company declined to respond to my request. Another company was incorrectly identified as a manufacturer of triclosan containing kitchen products.