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April 7, 2011

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

Re: Petition for Ban on Triclosan, Federal Register, Vol. 75, No. 235, Wednesday, December 8, 2010: Docket Identification Number EPA- HQ- OPP- 2010-0548

Dear Dr. McMahon:

The Consumer Healthcare Products Association (CHPA) is grateful for the opportunity to submit comments to the Environmental Protection Agency (EPA) addressing the recent petition from Food & Water Watch and Beyond Pesticides (hereafter referred to as "the petitioners") entitled "Citizen Petition for a Ban on Triclosan." While we applaud the petitioners' mission to seek to protect the public health, we believe the petitioners' assessment of 2,4,4' –trichloro-2'-hydroxydiphenyl ether (Triclosan) is incomplete and flawed. Therefore, we ask EPA to seriously consider the scientific evidence provided within this letter and the letter provided by the American Cleaning Institute (ACI)[1] and reject the petition to ban Triclosan and to suspend re-registrations.

The Consumer Healthcare Products Association (CHPA), founded in 1881, is a member-based association representing the leading manufacturers and distributors of nonprescription, over-the-counter (OTC) medicines and dietary supplements. CHPA members' products provide millions of Americans with safe, effective, and convenient therapies for the treatment and prevention of many common ailments and diseases. CHPA is committed to promoting the increasingly vital role of OTC medicines and dietary supplements in America's healthcare system through science, education, and advocacy.

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Triclosan is a common ingredient added to certain consumer products to reduce or prevent bacterial infection. CHPA member companies manufacture topical antiseptics such as hand wash and patient preoperative preparations as well as oral healthcare products for antigingivitis/antiplaque; these are FDA-regulated OTC products which can contain triclosan as an active ingredient. For millions of consumers and healthcare practitioners, these products play a vital role in maintaining daily hygiene and preventing the spread of bacteria in the home, workplace and healthcare settings. The petitioners failed to present new relevant research and failed to demonstrate their claim that triclosan "poses an actual and imminent threat to human health and the environment."

CHPA has provided comments below and refers EPA to ACI's letter submitted to the Docket Identification Number EPA- HQ- OPP- 2010-0548 for a more comprehensive analysis. The ACI letter, submitted in parallel, also references the existing data supporting our position for triclosan to remain as an active pharmaceutical ingredient.

Regulation of Triclosan:

The FDA and EPA both have regulatory authority over the ingredient triclosan depending on the claims that are made; neither FDA nor EPA alone regulates this ingredient. Triclosan is used in many industries, but the FDA has sole authority to declare a chemical entity such as triclosan or drug product containing triclosan as safe and effective for human use while the EPA regulates the antimicrobial uses of triclosan when used as a bacteriostat, fungi stat, mildew stat, and deodorizer.[2] The Petitioners erroneously suggest that EPA alone has the authority to regulate triclosan. However, neither agency should change regulation without consulting and interacting with the other. CHPA recommends that FDA and EPA continue to strengthen their partnership and communication regarding the regulation of triclosan.

Safety Analysis:

FDA's Center for Drug Evaluation and Research (CDER) maintains a selection of guidance documents for specific drug categories and a robust and rigorous process for determining the safety of a pharmaceutical product or product ingredient, inclusive of thorough toxicological review.

The EPA has evaluated and continues to evaluate all current EPA-registered uses of triclosan through an established Regulatory Eligibility Decision (RED) process. This process is thorough and summarizes the human health and environmental exposure and associated risks of triclosan. Through a 4-phase public vetting activity, EPA was able to determine the toxicological effects, product and residue chemistry and occupational/residential exposure of triclosan. A full literature review was also

completed and used in determining the re-registration eligibility. EPA used the available National Health and Nutrition Survey (NHANES) from the Center of Disease Control and Prevention (CDC) to effectively gauge the risks associated with indirect dietary and water exposure.

The 2008 EPA assessment of triclosan incorporated the 2003-2004 NHANES measurements of urinary concentrations of the U.S. population; therefore, the 2008 assessment was inclusive of all triclosan-related exposures.

Also, with regards to concentrations found in urine, the Centers for Disease Controls and Prevention (CDC) have stated "Finding measurable amounts of triclosan in urine does not mean that the levels of triclosan cause an adverse health effect. Biomonitoring studies on levels of triclosan provide physicians and public health officials with reference values so that they can determine whether people have been exposed to higher levels of triclosan than are found in the general population. Biomonitoring data can also help health scientists plan and conduct research on exposure and health effects."[3]

EPA determined that, with the exception of preservative use of triclosan in paints and stains, pesticides containing triclosan met the statutory safety standard in Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), provided that risk mitigation measures as outlined in the RED were implemented, confirmatory data gaps were addressed, and label amendments were incorporated as presented in the RED document. CHPA supports EPA in its decision to undertake another comprehensive review of triclosan which is planned for 2013 and will include all new and planned research, ten years earlier than originally planned. The petitioners do not offer EPA any justified reason to accelerate further their plan for reviewing the RED in 2013.

The re-registration process established by EPA ensures that current environmental safety standards are applied to older pesticides to mitigate risks "without disrupting unnecessary agriculture, public health, or vital use."[4]

In its re-registration review, EPA considered all available data on triclosan, including data on[5]

- endocrine effects,
- developmental and reproductive toxicity,
- chronic toxicity, and
- carcinogenicity

In addition, FDA is working to incorporate the most up-to-date data and information into the regulations that govern the use of triclosan in drug products. FDA will communicate the findings of its review to the public in spring 2011. FDA is "engaged in ongoing scientific and regulatory review of this ingredient [and does not] recommend changing consumer use of products that contain triclosan at this time."[6]

The petitioners made a variety of claims in their "Summary of Major Scientific Points" that CHPA would like to clarify and address.

Endocrine disruption:

Endocrine disruption is a key scientific issue that has been and will continue to be investigated for triclosan and triclosan-containing products. However, the petitioners do not provide sound justification behind their "statement of scientific grounds" that "the ubiquity of triclosan results in endocrine disruption." The petitioners point to findings of "some evidence" of endocrine disruption effects in studies conducted on male juvenile rats by EPA. Although animal studies have shown that triclosan could alter human hormone regulation, data showing effects in animals does not always predict effects in humans. FDA has also stated this fact regarding triclosan animal studies.[6] The petitioners fail to show that the results from the referenced animal studies translate to human.

Moreover, extensive studies have shown that triclosan does not cause endocrine disruption in humans. CHPA recognizes the ACI for developing a letter similar to this one that delineates these studies and the results.[1]

Development of EPA's Endocrine disruption screening program is well underway. Over the past several years, chemicals have been identified and added to a list to prioritize for screening and testing. These assays have also been developed and validated. In addition, EPA understands the importance of peer review and evaluation which is critical to all science- and risk-based decisions to improve the overall quality, credibility, and acceptability of regulatory decisions.

Bacterial Resistance:

The petitioners have highlighted triclosan as an ingredient that "promotes" bacterial resistance to antibiotics medications and cleansers. They also claim that through the use of triclosan-containing products, bacteria resistant to triclosan may create resistance to other antimicrobials and antibiotics (cross-resistance or co-resistance). The petitioners made these claims based on language from work that provided no substantial clinical evidence behind the claims. The original authors used terminology such as "potential" and "possible."[7,8]

The petitioners also neglected to reference literature that provides studies demonstrating that triclosan usage and exposure does not lead to bacterial resistance. For example, penicillin entered the market in 1941 and remains one of the most frequently-used antibiotics in the US. Despite this trend, we have not yet seen Group A Streptococci become resistant to penicillin in people's throats. Other resistances have taken over 40 years to build.[4]

Wastewater, Sludge and Food Contamination/Aquatic and Other Ecosystem Impacts:

The environmental fate and ecological risks have been evaluated by the EPA. Based on the current available data, EPA has found triclosan to be immobile in soil and nonvolatile in soil and surface water. EPA is also evaluating the impact to the aquatic environment and have found a low to moderate bioaccumulation effect on aquatic life forms. Risk quotients and levels of concern have been studied for triclosan using a qualitative risk assessment involving monitoring data in waterways and toxicity values. The agency also developed a consumer environmental model for triclosan in the surface water; the model revealed that the estimated levels of triclosan did "not exceed the concentrations of concern for acute risk for aquatic organisms and plants."[5] EPA also highlights research and studies that accredit aerobic biodegradation as the principle and most efficient degradation pathway for triclosan.[5]

The EPA has also stated that they consider that there is a low probability of triclosan entering the wastewater and surface water from consumer household antimicrobial use.[5]

Efficacy:

EPA's regulation of efficacy should only be focused around pesticide efficacy, not food- related benefits and drug efficacy. A pesticide is deemed efficacious "if it is killing what it claims to kill." [5]

The efficacy of triclosan has been demonstrated to the EPA for the products the agency regulates. The petitioners present no information that draws into question EPA's conclusions. Although not regulated by EPA, the petitioners present views on the efficacy of antibacterial hand wash products that are not supportable by the weight of evidence.

Through its well-established regulatory processes, FDA's monograph for many topical antiseptics containing triclosan has reached pending final monograph status. Triclosan-containing antibacterial hand washes provide a public health benefit by reducing pathogenic bacteria on the skin to a greater degree than plain soap and water. These findings are well documented. [9,10,11,12,13]

In 1997, FDA reviewed extensive effectiveness data on triclosan in Colgate Total toothpaste. The agency approved the effectiveness of this product in preventing gingivitis based on the evidence presented.[6]

Summary

CHPA would also like to take this opportunity to point out the potential unintended consequences that may be associated with the removal of triclosan from households and medical facilities. Triclosan remains a viable alternative to alcohol, which has been associated with hospital fires (FDA Safe Use

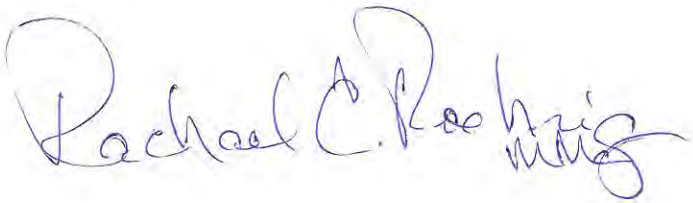
Initiative project). The risk in a healthcare setting of the transmission of infectious organisms and the susceptibility of the hosts is great. If these products were removed from this setting, the spread of bacteria and other organisms could endanger patients, consumers and healthcare practitioners. It is also imperative to control the spread of infectious organisms in the home and workplace.

Topical antiseptics and oral healthcare products for antigingivitis/antiplaque containing triclosan as an active pharmaceutical ingredient have been proved safe and effective by the FDA. One of the largest benefits the FDA provides through extensive investigation and testing is assurance that the products on the market are safe and effective. With regards to triclosan, the FDA continues to engage "in ongoing scientific and regulatory review of this ingredient [and does not] recommend changing consumer use of products that contain triclosan at this time."[6]

In conclusion, CHPA supports the American Cleaning Institute's position[1] (see ACI's submission addressing the Petition for Ban on Triclosan, Federal Register, Vol. 75, No. 235, Wednesday, December 8, 2010: Docket Identification Number EPA- HQ- OPP- 2010-0548) and urges the EPA to reject the recommendations in the petition made by the Food & Water Watch and Beyond Pesticides to suspend re-registrations and to ban triclosan from use in both EPA and FDA regulated products.

Please contact me if there are any further questions regarding these comments.

Sincerely,



Rachael Carlisle Roehrig, Ph.D.
Director, Technical & Scientific Affairs
Consumer Healthcare Products Association

[1] ACI's letter

[2] U.S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances. Reregistration Eligibility Decision for Triclosan http://nepis.epa.gov/EPA/html/DLwait.htm?url=/Adobe/PDF/P1001QGB.PDF

[3] http://www.cdc.gov/exposurereport/pdf/Triclosan_FactSheet.pdf

[4] Department of Health and Human Services, U.S. Food and Drug Administration, Center for Food and Drug Evaluation and Research, Non-prescription Drugs Advisory Committee Meeting transcript. October 20, 2005. http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4184T1.pdf p120

[5] http://www.epa.gov/oppsrrd1/REDs/factsheets/triclosan_fs.htm

[6] http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm205999.htm

[7] Levy 2001

[8] Yazdankhah 2006

[9] Zafar A.B, *et al.*, 1995. Use of 0.3 triclosan to eradicate an outbreak of MRSA in a neonatal nursery. *Am. J. Infect. Control.* 23:200-208.

[10] Webster J. *et al.*, 1994. Elimination of methicillin resistant *Staphylococcus aureus* from a neonatal intensive care unit after hand washing with triclosan. *J. Paediatr. Child Health*. 30: 59-64.

[11] Fischler G.E. *et al.*, 2007. Effect of hand wash agents on controlling the transmission of pathogenic bacteria from hands to food. *J. Food Protect*. 70: 2873-2877.

[12] Fuls, J.L. *et al.*, 2008. Alternative hand contamination technique to compare the activities of antimicrobial and non-antimicrobial soaps under different test conditions. *Appl. Environ. Microbiol.* 74:3739-3744.

[13] Kruszewski F.H. and J. F. Krowka 2011. Best Practices for Determining Efficacy of Antibacterial Hand Wash Products. Internal Medicine News Best Practices Supplement. January 15, 2011.