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June 28, 2010

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

Re: Efficacy Test Guidelines for Public Health Related Antimicrobial Pesticides, EPA-HQ-OPP-2009-0681, 75 *Fed. Reg.* 4380 (Jan. 27, 2010)

Dear Sir/Madam:

Public Employees for Environmental Responsibility ("PEER") appreciates the opportunity to comment on the four efficacy test guidelines for public health-related antimicrobial pesticide products that have been proposed by the United States Environmental Agency ("EPA"). These guidelines, developed by the EPA's Office of Prevention, Pesticides, and Toxic Substances ("OPPTS"), address efficacy testing for antimicrobial agents intended to be used on hard, inanimate, environmental surfaces, and which bear label claims as sterilants, disinfectants, or sanitizers.[1] According to the proposed guidelines, public health-related antimicrobials are defined as "products bearing claims to control organisms that may pose a threat to human health, either directly or through transmission of disease-causing organisms on environmental surfaces or the environment," in addition to those antimicrobial products "recommended for use in hospital or medical environments."[2]

A. Regulatory Background

Because of their public health implications, and especially in light of the fact that users cannot see whether these products kill bacteria, fungi, and viruses, the EPA rightly mandates that manufacturers of antimicrobial products supply efficacy data to support labeling claims and patterns of use as a precondition to registration under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA").[3] The EPA has upheld these

[1] *See* Pesticide News Story, *EPA Re-opening Comment Period on Product Performance Test Guidelines for Public Health Uses of Antimicrobial Pesticide Products*, United States Environmental Protection Agency, *available at* http://epa.gov/oppfead1/cb/csb_page/updates/2010/testguid-antim.html.

[2] UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES, PRODUCT PERFORMANCE TEST GUIDELINES, 810.2000 § (c)(1)(ii), *General Considerations for Public Health Uses of Antimicrobial Agents* (2009).

[3] *Disinfectants: EPA Lacks Assurance That They Work*, General Accounting Office, GAO/RCED-90-139, 2 (1990), *available at* http://archive.gao.gov/d23t8/142343.pdf.

efficacy data requirements despite that fact that FIFRA permits the agency to "waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining if the pesticide's composition is such as to warrant the proposed claims of efficacy."[4] Further, the EPA has invoked this grant of permission by issuing a general waiver of the review of labeling claims relating to pesticide efficacy, while explicitly carving out an exception for public health-related antimicrobials.[5] Specifically, the EPA has waived "all requirements to submit efficacy data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health, and whose presence cannot readily be observed by the user, including, but not limited to, microorganisms infectious to man in any area of the inanimate environment."[6] This exception clearly points to the special role of antimicrobial pesticides in protecting public health, most particularly in clinical settings.[7]

B. The Draft Guidelines Are Non-Binding and Therefore Do Not Adequately Protect Consumers from Reliance on Ineffective or Insufficiently Effective Public Health-Related Pesticide Products and from False or Deceptive Product Efficacy Claims

We applaud the EPA for proposing a series of test guidelines for efficacy data on public health-related antimicrobial pesticides that are designed to correct prior deficiencies in scientific methodologies and protocols, and to bring greater clarity to the procedures for effectively and fairly testing product performance. However, we are unclear why these procedures remain non-binding. It seems profoundly counterintuitive for the EPA to require efficacy pre-registration data for antimicrobials under the auspices of protecting public health, and yet to permit departures from the testing procedures it has deemed most credible for efficacy testing. In other words, if these testing procedures are not standardized according to the scientific methods that OPPTS has deemed most effective, how can the EPA ensure that antimicrobial products are actually fulfilling their designated commercial purposes? Such uncertainty surrounding product efficacy poses a risk to public health, especially in clinical settings, where antimicrobial products are important tools for preventing infections in persons with weakened immune systems.[8]

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[4] 7 U.S.C. § 136a(c)(5) (1996).

[5] *See* 40 C.F.R. § 158.640(b)(1) (2001); *see also Jarman v. United Industries Corp.*, 98 F. Supp. 2d 757, 761 (S.D. Miss. 2000).

[6] 40 C.F.R. § 158.640(b)(1)..

[7] *See* R. Douglas Scott II, *The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention*, CDC National Center for Preparedness, Detection, and Control of Infectious Diseases, (Mar. 2009), *available at* http://www.cdc.gov/ncidod/dhqp/pdf/Scott_CostPaper.pdf (discussing how, according to estimates made by the Centers for Disease Control and Prevention, there is a 4.5% chance of health care-associated infection for each hospital admission, amounting to well over a million infections and tens of thousands of deaths annually in the United States, and costing billions of dollars).

[8] *See* Alexandra Scranton, *Disinfectant Overkill: A Report by Women's Voices for the Earth*, 4, (Nov. 2009), *available at* www.womenandenvironment.org/.../disinfectants/Disinfectant%20Overkill.pdf.

From a consumer protection standpoint, this regulatory inadequacy would seem to implicate section 45 of the Federal Trade Commission Act ("FTCA"), which contains a general prohibition on unfair or deceptive acts or practices in or affecting commerce.[9] This provision can be triggered by a material representation that is likely to mislead a consumer acting reasonably under the circumstances.[10] Express product claims, such as claims about efficacy, are presumed to be material, and moreover, intent to deceive is irrelevant.[11] In the case of antimicrobials, it is at least questionable whether a product that claims to disinfect, sanitize, or reduce or mitigate the growth or development of microbiological organisms that pose a threat to public health actually achieves that purpose in the absence of a standardized efficacy testing regime that holds manufacturers to consistent and reliable scientific standards. Thus, greater oversight, including mandatory testing standards, is necessary to ensure that consumers—especially those who are sick or otherwise immunocompromized—are protected from false or deceptive claims about the efficacy of public health-related antimicrobial merchandise.

C. The Draft Guidelines Do Not Adequately Consider the Environmental and Human Health Risks Posed by Antimicrobial Pesticides

In addition, we strongly urge the EPA to broaden its focus with respect to antimicrobial pesticide products by holding manufacturers to a higher standard not only for the efficacy testing of public health-related antimicrobials, but also through implementation of an improved set of data requirements that better assess the environmental and human health impacts of all antimicrobial agents. In 2008, the EPA itself conceded that antimicrobial pesticides in wide use are not adequately tested for their effects on the environment and on human health, and proposed a series of new and amended data requirements "intended to further enhance the [a]gency's ability to make regulatory decisions about the human health and environmental fate effects of antimicrobial pesticide products."[12] With a clear emphasis on down-the-drain fate, in particular, four new data requirements would also inform a screening-level assessment of the impacts of antimicrobials that reach wastewater treatment plants.[13]

However, the EPA has yet to promulgate these requirements as a final rule, which we find regrettable. Under FIFRA, the EPA is explicitly required to consider, in evaluating any pesticide for registration, whether it "will perform its intended function

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[9] *See* 15 U.S.C.A. § 45(a)(1) (2006).

[10] *See Cliffdale Assocs.*, 103 F.T.C. 110, 164-65 (1984).

[11] *See Warner-Lambert Co. v. FTC*, 562 F.2d 749, 763 n.70 (D.C. Cir. 1977); *F.T.C. v. Pantron I Corp.*, 33 F.3d 1088, 1095-96 (1994).

[12] Data Requirements for Antimicrobial Pesticides, Proposed Rule, 73 Fed. Reg. 196, 59,382, 59,383, (proposed Oct. 2008) [hereinafter 2008 Proposed Rule].

[13] *See id.*

without unreasonable adverse effects on the environment."[14] FIFRA defines this standard to encompass, *inter alia*, "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[15] Thus, if the EPA fails to require the submission of adequate data on environmental and human health impacts, and therefore cannot give adequate consideration to those impacts when weighing the costs and benefits of registering a given pesticide, it neglects a clear statutory mandate.

We also take issue with the scope of the proposed rule, which, if adopted, would apply only to future registrations of antimicrobial pesticides, and generally not apply to existing registrations.[16] This is problematic in light of the fact that the EPA retains significant ongoing discretionary authority with respect to all pesticide registrations for the purpose of determining whether registered products continue to meet FIFRA's statutory standards.[17] For example, during reregistration, manufacturers are required to "submit additional data and studies regarding the risks and benefits associated with [a given] pesticide," and the EPA must cancel or suspend any existing registrations that "cause[] unreasonable adverse effects to people or the environment when used according to the product labeling."[18] For a number of reasons, it is important that the EPA adhere to the "unreasonable adverse effects" standard—basing that standard on the best possible data achieved through mandatory testing standards—during the approval process for new antimicrobial products, as well as during any reevaluations of existing registrations. This is particularly crucial in the case of public health-related antimicrobial pesticides, due to their rapid proliferation into healthy households in what has quite accurately been deemed an "antibacterial craze," and in light of significant evidence that they pose serious environmental and human health risks.[19]

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[14] 7 U.S.C. § 136(a)(c)(5).

[15] 7 *Id.* at § 136(bb).

[16] *See* 2008 Proposed Rule at 59,388 (stating that "[t]he Agency does not intend to apply these requirements automatically or routinely to all existing pesticide registrations").

[17] *See* 7 U.S.C. §§ 136a(d)(2) (the EPA may change the use classification of any pesticide when necessary to prevent unreasonable adverse effects on the environment), 136(a)(c)(2)(b)(1) (EPA may determine that additional data is required to maintain an existing pesticide registration), 136(d) (EPA has the authority to change, cancel, restrict, or immediately suspend registered pesticides, pesticide labeling, or particular uses); *see also Beyond Pesticides/National Coalition Against the Misuse of Pesticides v. Whitman*, 294 F. Supp. 2d 1, 3 (D.D.C 2003) (noting how, "[o]nce a pesticide is registered, FIFRA provides review procedures in order for EPA to continually reevaluate a pesticide's risks and benefits").

[18] *Whitman*, 294 F. Supp. 2d at 3-4; *see also* 7 U.S.C. § 136a-1(a)(2) (mandating that the EPA may not reregister a pesticide unless "the requirements of section 136a(c)(5) of this title have been satisfied").

[19] Stuart P. Levy, *Antibacterial Household Products: Cause for Concern*, Tufts University School of Medicine, *available at* http://www.cdc.gov/ncidod/eid/vol7no3_supp/levy.htm (stating that "[t]he recent entry of products containing antibacterial agents into healthy households has escalated from a few dozen products in the mid-1990s to more than 700 today").

Public health-related antimicrobial agents, initially developed for hospital and other clinical settings, have become ubiquitous as the result of clever marketing that has convinced many consumers, especially parents, that it is imperative to purge their homes of all germs. Today, these pesticides are found in products ranging from household cleaners, to mattresses and bedding, cosmetics, toys, toothpaste, and even to chopsticks.[20] And yet research has shown that some of the most common antibacterial agents present substantial risks to the environment and to human health, which we feel the EPA neglected to adequately consider during its initial registration of these chemicals. For example, studies suggest that triclosan, one of the most prevalent antibacterial chemicals used in consumer products, is an endocrine disrupter that may interfere with proper thyroid hormone function, which is crucial for brain and nervous system development in infants and children, and which regulates energy balance in adults.[21] Other studies point to a correlation between too much hygiene and an increased rate of allergies, asthma, and eczema.[22] This "hygiene hypothesis," which has been gaining traction in scientific and medical circles, suggests that an "antigenically rich (dirty) environment may be essential for normal immune maturation preventing atopic disease."[23] There is also growing concern that continued overuse of antimicrobial products will create strains of bacteria, known as "superbugs," that are immune to the effects of therapeutic antibiotics, consequently denying scientists and doctors an essential tool in protecting vulnerable populations, including the sick and the elderly.[24] Moreover, from an environmental perspective, antimicrobial chemicals are often washed down the drain and end up in our rivers, lakes, and streams, proving toxic to fish and other aquatic animals and aquatic plants.[25]

In light of these and other concerns, U.S. Representative Edward J. Markey, Chairman of the Energy and Environment Subcommittee of the Energy and Commerce Committee, has called for a ban on many applications of triclosan, which would reduce human and environmental exposure to one of the most widely used, and dangerous, antimicrobial chemicals currently available.[26] However, it is vital that the EPA itself

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[20] *See id.* There are currently more than 5,000 antimicrobial pesticides registered with the EPA. However, the Food and Drug Administration ("FDA") regulates antimicrobials when they are used on or in the human body. *See* Beyond Pesticides - Antimicrobials and Antibacterials, http://www.beyondpesticides.org/antibacterial/ (last visited June 15, 2010).

[21] *See* Beyond Pesticides Daily News Blog, *Triclosan Fact Sheet*, http://markey.house.gov/docs/triclosan_information_final.pdf (last visited June 15, 2010).

[22] *See* Levy, *supra* note 19.

[23] Gert Folkerts, Gerhard Walzl, and Peter J. M. Openshaw, *Do Common Childhood Infections "Teach" the Immune System Not to be Allergic?*, 21 IMMUNOL TODAY, 118, 120 (2000).

[24] *See* Scranton, *supra* note 8, at 6.

[25] *See Pesticide in Soap, Toothpaste, and Breast Milk—Is It Kid-Safe?: Triclosan Toxicity*, Environmental Working Group, *available at* http://www.ewg.org/node/26701.

[26] *See* Beyond Pesticides Daily News Blog, *FDA Acknowledges Adverse Effects of Triclosan, U.S. Rep Urges Ban* (Apr. 9, 2010), *available at* http://www.beyondpesticides.org/dailynewsblog/?p=3420.

preempt and mitigate such harmful exposures by making environmental and human health impacts integral to its assessments of whether antimicrobial pesticides can be marketed for consumer use at the outset, and of whether existing products should be allowed to remain on the market. These actions, in turn, can only be accomplished if the EPA requires manufacturers to supply comprehensive human health and environmental fate data for antimicrobials as a precondition to product registration and reregistration under FIFRA. We strongly urge the EPA to take this crucial step by adopting up-to-date requirements for the submission of this data, and further, to refrain from registering or reregistering any antimicrobial pesticides until these improved requirements have been implemented.

D. The EPA Has Failed to Adequately Consider Whether Public Health-Related Antimicrobial Pesticides Benefit Average Consumers

In our view, the proposed ban on triclosan also points to an additional failing on the part of the EPA, namely, that it has neglected to consider whether public health-related antimicrobials actually generate appreciable health benefits for average consumers. Products containing these chemicals were originally designed for clinical use in protecting vulnerable patients in hospitals, nursing homes, and other health care facilities from infectious disease-causing organisms.[27] And while we do not question the assertion that "[t]argeted disinfection with antimicrobial chemicals is an important public health strategy in the hospital [or other clinical] setting that can reduce the spread of serious disease," there is little evidence to suggest that average consumers do in fact benefit from the use of these products.[28] Indeed, the American Medical Association has explicitly stated that, "despite their recent proliferation in consumer products, the use of antimicrobial agents such as triclosan in [these] products has not been studied extensively. No data exist to support their efficacy when used in such products or [to support] any need for them."[29] Further, the FDA has conceded that, in the case of triclosan specifically, "[a]t this time, the agency does not have evidence that [its presence] in antibacterial soaps . . . provides any benefit over washing with regular soap and water."[30]

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[27] *See* Levy, *supra* note 19.

[28] *See* Scranton, *supra* note 8, at 4; *see also* Antibacterial Agents Q&A, Alliance for the Prudent Use of Antibiotics, *available at* http://www.tufts.edu/med/apua/Q&A/Q&A_antibacterials.html#6 [hereinafter Antibacterial Agents Q&A]. "A certain few [antibacterial] consumer products have demonstrated effectiveness for specific conditions: antibacterial toothpaste helps control periodontal (gum) disease; antibacterial deodorants suppress odor-causing bacteria, and antidandruff shampoos help control dandruff. However, to date, there is no evidence to support claims that antibacterials provide additional health benefits when used by the general consumer." Antibacterial Agents Q&A.

[29] AMERICAN MEDICAL ASSOCIATION, REPORT 2 OF THE COUNCIL ON SCIENTIFIC AFFAIRS, NO. A-00, *Use of Antimicrobials in Consumer Products* (2000).

[30] Consumer Update, *Triclosan: What Consumers Should Know*, U.S. Food and Drug Administration, *available at* http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm205999.htm.

The EPA cannot disregard such information. As discussed, it is statutorily tasked with undertaking an analysis of risks and benefits when considering whether to register or reregister a pesticide for consumer use.[31] In the case of public health-related antimicrobials, however, the EPA's "benefit" calculation—at least insofar as it relates to average consumers—seems largely based on presumption. The EPA must amend this approach, by requiring manufacturers of public health-related antimicrobial pesticides to not only supply data that assesses the environmental and human health impacts of their products, but also data which supports any claims to produce general health benefits. This is crucial, because, if these chemicals produce little or no benefits to average consumers over safer alternatives, it is unreasonable to accept the human health and environmental risks they pose. Thus, we believe that the EPA should restrict the use of currently registered public health-related antimicrobial pesticides to clinical settings, and refrain from approving any pending or future registrations for use in general consumer products, unless and until the submission of such data is made mandatory, and the data itself supports additional uses.

E. Conclusion

In sum, we strongly urge the EPA to take action on the following recommendations: (1) make the proposed efficacy test guidelines mandatory in order to protect consumers, particularly those who are sick or otherwise immunocompromized, from the health risks associated with reliance on ineffective or inadequately effective public health-related antimicrobial pesticide products, and from false or deceptive claims about the efficacy of these products; (2) adopt up-to-date requirements for the submission of data on the environmental fate and environmental and human health impacts of antimicrobial pesticides; (3) refrain from registering or reregistering additional antimicrobial pesticides until these requirements are in place; and (4) limit the use of currently registered antimicrobial pesticides to clinical settings, and decline to approve any pending or future registrations for general consumer use, unless and until data requirements are implemented which support additional uses by demonstrating appreciable health benefits to average consumers.

[31] *See* 7 U.S.C. §§ 136(bb), 136a-1(a)(2).

Respectfully,

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