

Triclosan Hazards...Continued

Trade group misleads on common antibacterial agent

By John Kepner

In the Fall 2004 issue of *Pesticides and You* (Vol. 24, No. 3), Beyond Pesticides published “The Ubiquitous Triclosan,” an article examining the health and environmental effects, efficacy, regulatory history and alternatives to the common antibacterial agent triclosan. In a nutshell, the article (which is available online at www.beyondpesticides.org/pesticides/factsheets) reports on data that show triclosan and similar antibacterial agents affect the central nervous system, are linked to increased allergies and asthma, may promote bacterial resistance, cause environmental damage, may degrade into dioxin, and in many cases are no more effective against germs than regular soap and water. Ever since its publication, feedback from members and the public has been pouring in to Beyond Pesticides.

As you can read in the *Mail* section of this issue of *Pesticides and You* (see page 2), Tony Tweedale of Missoula, MT wrote to say that, in addition to being converted to dioxin when exposed to UV light as we reported, the initial structure of triclosan itself is very similar to dioxin. Mr. Tweedale writes, “The structure of triclosan is very close to that of dioxins, especially to the

most toxic dioxin (“TCDD”)...In fact, the certification of the purity of triclosan for its U.S. manufacturer can only state that it contains ‘less than 1% total dioxins and furans.’ That is a massive source of such a toxin, especially in intimate products...” Also after reading the article, Alice Sheppard, PhD, from Presque Isle, ME read the label of her deodorant and found that to her surprise it contained triclosan. She wrote to the manufacturer, outraged that she was misled by their claim that it was “natural, safe, gentle, and effective.”

While the direct feedback on the triclosan article has been very positive and appreciative, it also managed to spark a negative reaction from the Soap and Detergent Association (SDA). The trade group that represents manufacturers of cleaning products that often contain triclosan, issued a press release claiming that Beyond Pesticides’ triclosan article was sounding a “false alarm.” Their response does not address the vast volume of independent scientific assessments raising problems (30 cited in the Beyond Pesticides review), but points to a few equivocal studies, two done in collaboration with a soap manufacturer, and then misrepresents these findings.

Soap and Detergent Association (SDA) Defends Triclosan Beyond Pesticides Responds

Editor's Note: The Soap and Detergent Association issued a press release on December 22, 2004 charging that Beyond Pesticides article on triclosan is a “false alarm.” What follows is a portion of SDA's release and Beyond Pesticides' response.

Soap and Detergent Association Washington, DC, December 22, 2004

An activist group's report attacking a major antibacterial ingredient used in some consumer products is nothing more than a “false alarm,” according to the Soap and Detergent Association (SDA). SDA, which represents manufacturers of cleaning products and their ingredients, was responding to a statement issued by the activist group Beyond Pesticides concerning use of the ingredient triclosan. SDA rebutted the group's claims that triclosan promotes antibiotic resistance and poses other health risks.

Triclosan has been safely and effectively used in hygiene products for nearly 40 years. The use of these beneficial hygiene products should not be discouraged based on reports that do little more than stir up hypothetical fears rather than describe real-life, present day scenarios. The activist group's report is little more than a false alarm that could unnecessarily scare consumers. In recent years, several national, regional, and inter-governmental agencies

have reviewed the available data on antibiotic resistance. None have identified resistance associated with the use of antibacterial products or compounds as a concern under current conditions of use (see examples and response in box below).

Beyond Pesticides response

Beyond Pesticides finds the Soap and Detergent Association's December 22, 2004 press release, “SDA Responds to Activist Group's ‘False Alarm’ on Key Antibacterial Ingredient,” very misleading. While the trade association did little to counter the links between triclosan and its adverse impacts on human health and the environment or its lack of efficacy in real world use, such as hand washing, it did focus a lot of attention on antibacterial resistance. Beyond Pesticides believes the claims in SDA's press release, however, are full of half-truths and misinformation.

Beyond Pesticides' review of the scientific literature in “The Ubiquitous Triclosan” includes 67 citations with multiple findings of concern regarding health and environmental effects. SDA, on the other hand, not only points to a handful of studies, some of them produced by manufacturers with financial interest in triclosan's continued use, but it does so with misleading characterizations of the facts.

Triclosan: Point – Counterpoint

Editor's Note: What follows are SDA's claims distributed in a press release in response to Beyond Pesticides' article "The Ubiquitous Triclosan," and Beyond Pesticides' rebuttal.

- 1. SDA claim:** In June 2002, a European Commission Scientific Steering Committee completed a comprehensive and thorough scientific review and analysis of data on antibiotic resistance regarding triclosan. The panel reported that, "There is no convincing evidence that triclosan poses a risk to humans or to the environment by inducing or transmitting antibacterial resistance under current conditions of use."

BP response: SDA cites a European Commission study that finds no risk of antibacterial resistance. However, this conclusion is based specifically on examining triclosan products in their pure form at "high biocidal concentrations." The same report also states that bacterial resistance may be a concern at sub-biocidal and bacteriostatic concentrations, such as residues that remain up to 12 hours following a hand-washing or tooth-brushing, wastewater effluent that is emitted into waterways (triclosan is not removed by wastewater treatment plants), and impregnated plastics.

- 2. SDA claim:** Research presented by University of Manchester (UK) scientists Peter Gilbert and Andrew McBain reported that, "The risk of bacteria developing antibiotic resistance after exposure to the biocide triclosan may not be as great as previously believed. Indeed a number of field studies conducted of homes and clinics were unable to link antibacterial use patterns with changes in resistance." The research was presented at the 104th General Meeting of the American Society for Microbiology in May 2004.

BP response: SDA cites a presentation of a British study to back up its assertion that bacterial resistance is not as bad as once thought. While this study did not find resistance in all bacterium, it did find that repeated exposure to triclosan causes resistance in two potentially deadly types of bacteria—*Escherichia coli* and *Klebsiella* bacteria.

- 3. SDA claim:** A scientific review written on the use of triclosan by noted researcher Denver Russell—published in the May 2004 *Journal of Antimicrobial Chemotherapy*—stated that "comprehensive environmental surveys have not demonstrated any association between triclosan usage and antibiotic resistance."

BP response: SDA cites another study from the UK, which states that "comprehensive environmental surveys" have not shown resistance. However, the study does acknowledge lab studies that show resistance and in the very next sentence suggests that "frivolous and unnecessary" triclosan uses should be eliminated. Given the fact that it works no better on hands than ordinary soap and water, Beyond Pesticides believes that most home uses would fall in the unnecessary category.



Some common household products that contain triclosan.

- 4. SDA claim:** Research from the September 2003 issue of *Applied and Environmental Microbiology* reported that the "emergence of antibiotic resistance through triclosan in the kitchen is highly improbable."

BP response: SDA's citation essentially references the same data as #2, only this time the print version, rather than proceedings from a meeting. The journal citation does reveal that Drs. Gilbert and McBain did their research in collaboration with Procter and Gamble, a company with a financial stake in the success of triclosan.

- 5. SDA claim:** A study in the October 2003 *Journal of Applied Microbiology* "refutes widely publicized, yet unsupported, hypotheses that use of antibacterial products facilitates the development of antibiotic resistance in bacteria from the home environment."

BP response: SDA cites a study examining the cross-resistance of triclosan and antibiotics (exposure to triclosan leads to antibiotic drug resistance). This is a case of different studies supporting different sides of an issue. While the one study SDA cites does not show cross-resistance to the particular drugs chosen for the study, Beyond Pesticides' article cites two studies that do show such resistance is likely to occur.

- 6. SDA claim:** "In addition, no credible evidence has been presented to date that triclosan could be converted into a harmful dioxin in waterways nor that it would pose any risk for humans or the environment." Beyond Pesticides' report references work conducted by researchers at the University of Minnesota, which in fact states that exposing triclosan in water to sunlight "produces only a very mildly toxic chemical—perhaps 150,000 times less toxic than the types of dioxin considered the most dangerous."

BP response: SDA refers to University of Minnesota research, stating that the study shows that UV light converts

Reflections by Former EPA Attorney James Handley on Triclosan and the EPA Review

In addition to the response from SDA and the letters published in the Mail section, Beyond Pesticides also received the letter below from James Handley, a former EPA enforcement attorney. Mr. Handley shares his insights and experience litigating an enforcement case against the manufacturers of Microban (triclosan) for making false claims, which are illegal under federal pesticide law. In addition to examining problems specific to triclosan, his letter examines problems with the entire pesticide regulation process.

Thanks for the excellent article "The Ubiquitous Triclosan." Triclosan is indeed ubiquitous and Microban International, the manufacturer of a triclosan-based plastic additive which has been used in toys, sandal foot beds, public railings, etc., has made it more so. Their leading products, "Microban Plastic Additive B," is marketed for protection against human pathogens, which is far beyond any scientific support accepted by EPA in registering this pesticide. EPA registration supports only *bacteriostatic* effects which means that Microban Additive B has been shown to control the growth of organisms that cause aesthetic or economic damage to the treated article, but *not* micro-organisms infectious to humans.

Beginning in 1998, Robert Darnell, Brenda Mosley and I initiated and litigated an enforcement case against Microban for making health-related claims that are not supported by its EPA pesticide registration. The company's liability was hardly in doubt: we even obtained copies of the registration documents that appeared to have been altered to omit crucial restrictive language; apparently these alterations were made in order to market Microban's alleged health benefits to companies such as those that make children's toys. In 2004, EPA enforcement finally prevailed on all issues in its second appeal of this matter before the Environmental Appeals Board. The Board upheld EPA's interpretation of the *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA) penalty provisions: as the literal language of FIFRA §12(a)(1)(B) states, each *sale or distribution* is a violation, therefore counting the number of *documents* in which Microban's unlawful claims were made undercounts violations. As a result, the Board affirmed EPA enforcement's assessed penalty of \$160,500 for 32 violations of FIFRA, one for every shipment made to the toy manufacturer.

From my point of view as a former EPA enforcement attorney (which may or may not be the view of EPA), this case illustrates a number of interesting points: Most obvious was the huge effort required to mount a successful prosecution of FIFRA violations. The case took months of preparation and had to be appealed twice before the legal issues relating to how FIFRA counts violations were properly resolved. Also striking is the disproportionately small penalty when viewed in context of the companies involved, the economic gains obtained and the potential harm to public health and the environment. Triclosan is a very profitable product and is being used to obtain competitive advantage in the marketing of a wide range of products mentioned in your article. Yet the benefits for most of its uses are certainly not evident in its EPA registration, if they exist at all.

EPA generally does not explicitly consider benefits (or the lack thereof) in the context of its registration process. FIFRA obliges EPA to register a pesticide if it does not cause "unreasonable adverse effects." (EPA has decided that the marketplace can adequately determine whether or not a pesticide is effective.) The exception is for pesticides for which health claims are made. Microban has avoided the need to provide efficacy data by registering its Additive B only as a bacteriostatic -- i.e., for the very limited purpose of controlling microorganisms in the treated article. Thus, no one should think that EPA's registration of Microban implies that EPA has found the product to be effective or useful, much less that its benefits outweigh its risks. EPA simply does not consider that for bacteriostatic agents.

As the Microban case held, any pesticidal claims beyond bacteriostatic claims are unlawful because for whatever reason, the company has not provided supporting data for those claims in the registration. (As you note, Microban is also regulated by FDA for "drug" uses mentioned in your article, and for those, it is my understanding that a more explicit risk/benefit analysis *does* apply.)

Thanks again for an excellent article. I hope as you make more consumers aware of the very limited situations in which triclosan may be beneficial, and the many more situations where its use is either not beneficial or potentially harmful, its use will become far less ubiquitous.

triclosan into a "very mild" form of dioxin. While it is true that dioxins have a range of toxicity and 2,8-DCDD falls on the less harmful end of the spectrum, the study's author, Kristopher McNeill, PhD, warns, "Repeated exposure to chlorine [chlorinated water] could chlorinate triclosan. After chlorinated triclosan is discharged, sunlight could convert it into more toxic dioxins. Such a process might be a source of highly toxic dioxin in the environment."

Beyond Pesticides believes that misinformation such as that presented in SDA's press release misleads the public and contributes to the overuse of antibacterial agents such as triclosan. Beyond Pesticides does not argue against the use of antibacterial cleansers in all cases. Certainly hospitals, medical profes-

sionals and those with compromised immune systems depend on effective antibacterial agents. However, Beyond Pesticides believes that promoting the overuse of these chemicals is a disservice to the very people that depend on them the most, because of documented resistance. Most importantly, there are safer alternatives that SDA could promote when a sterile environment is needed.

Companies and governments around the world are rejecting triclosan because of the weight of scientific evidence identifying health and environmental problems. In Europe, the Danish, Finnish and German governments have encouraged citizens not to use such antibacterial products on a regular basis. In the UK, four major grocery chains have banned triclosan from their products.