



Triclosan Is More Regulatory Action Needed?

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National Association of Clean Water Agencies
National Pretreatment and Pollution Prevention Workshop
May 16, 2013

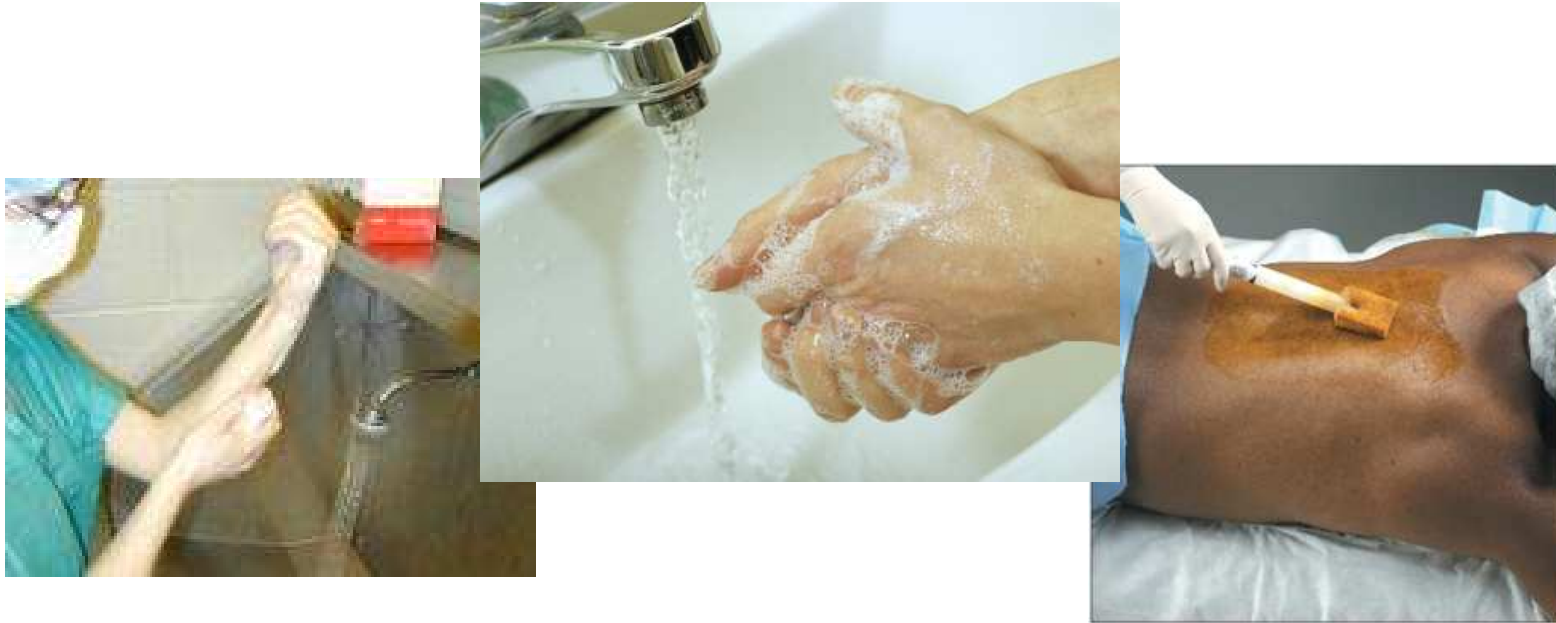
Antibacterials – Triclosan and Triclocarban



- Triclosan – 75% liquid hand soaps + other products.
- Triclocarban - >25% of bar soaps



Topical Antimicrobial Soaps



Regulated by the FDA through the Federal Food, Drug, and Cosmetic Act ("Food and Drug Act") prohibiting the marketing of drugs unless they are found to be safe and effective.

FDA monograph on topical antimicrobials



- **1974.** 1st Proposal To Establish a Monograph for OTC Topical Antimicrobial Products
- **1978** Tentative final order
- **1994** Amended Tentative final order
- **2010** Working on new amendments to proposed final rule

FDA Categorization



- I. Conditions under which antimicrobial products are generally recognized as safe and effective and are not misbranded.
- II. Conditions under which antimicrobial products are **not** generally recognized as safe and effective or are misbranded.
- III. Conditions for which the available data are insufficient to permit final classification at this time.

Active Ingredients Used in Healthcare (FDA categorization)



- Alcohol, 60-85% (I)
- Povidone-iodine, 5-10% (I)
- Hexachlorophene (II)
- Chloroxylenol (PCMX) (III)
- Quaternary ammonium compounds
 - Benzalkonium chloride (III)
 - Benzethonium chloride (III)
- Triclosan, <1% (III)
- *Chlorhexidine gluconate, 2 or 4% (ns)

Active Ingredients Used in Consumer Soapd (FDA categorization)



- Alcohol (I)
- Chloroxylenol (PCMX) (III)
- Quaternary ammonium compounds –
 - Benzalkonium chloride (III)
 - Benzethonium chloride (III)
- Triclocarban (III)
- Triclosan (III)

FDA regulations

- The topical antiseptic monograph at FDA has remained in draft form for over 35 years
- Through a loophole in the existing law, until the monograph is finalized, chemicals in category III (including triclosan and triclocarban) can be legally sold for consumer and health care use.

Concerns about triclosan – widespread human exposure



- More than 1 million pounds produced annually
- Absorbed across the skin, mucosa with a half life 11-12 hours.
- Found in >75% Americans surveyed by the CDC, exposure levels are increasing (Calafat, EHP, 2008)
- Volunteers brushing with triclosan toothpaste for 14 days, had dramatic rise in blood levels (average 450x). (Allymr, 2009)

Concerns about triclosan – unnecessary exposure



- No more effective than plain soap and water.
 - Community intervention studies, no significant reduction in viral or bacterial disease
 - No reduction of bacterial levels found on hands (Aiello, 2007)
- *“ At this time, FDA does not have evidence that triclosan added to antibacterial soaps and body washes provides extra health benefits over soap and water.”*

FDA Consumer Update

“Triclosan: What Consumers Should Know”

<http://www.fda.gov/forconsumers/consumerupdates/ucm205999.htm>

Concerns about triclosan - antibiotic resistance



- Potential to promote drug-resistant bacteria
- Triclosan-resistant bacteria isolated from residential and feedlot soil (Welsch, 2011)
- Studies show cross-resistance to ≥ 1 antibiotic for at least 1 bacteria species (Aiello, 2007)

E. coli, Salmonella enterica, Staph. aureus
Amp, Chl, Cipro, Ery, INH, Tet

Health Concerns about triclosan



- Tumor formation (FDA monograph)
- Hormone disruption (Crofton, 2007; Kumar, 2009; Stoker, 2010)
- Weakened muscles (Cherednichenko, et al. 2012)
- Associated with allergies (Clayton, 2011 and Savage, 2012)

Antimicrobials in the environment



- Neither triclosan nor triclocarban occur naturally
- Both are found in surface water, waste water and sewage sludge/biosolids.
- Concentrations of TCC downstream of sewage treatment plants (84 ± 110 ng/L) were significantly higher than samples taken upstream (12 ± 15 ng/L) (Sapkota, 2007)



Antimicrobials in sewage sludge



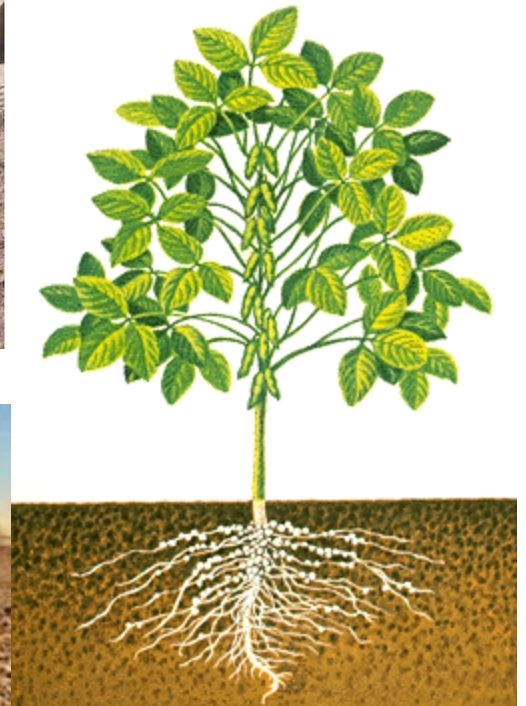
- Together make up 2/3 mass of pharmaceuticals and personal care products in sewage sludge. (McClellan, 2010).
- TCC concentrations 3x > triclosan in biosolids.
- Triclosan has been described as “the most abundant polychlorinated phenol ever found in wastewater sludge”



Triclosan in wildlife

- Interferes with survival and reproduction in crustaceans and may interfere with thyroid hormone in amphibians
- Bioaccumulates in fish
- Found in the bodies of wild bottlenose dolphins
- Triclosan has been shown to accumulate in earthworms living in biosolid-treated fields

Down the drain and into farm fields



(Wu, ES&T, 2010)

Antimicrobials in food?



Wu, et al. 2010



Aryal, et al. 2011



Macherius, et al. 2012



Unregulated antimicrobials



In lieu of any regulatory action,

What else can be done?

American Medical Association



"Despite their recent proliferation in consumer products, the use of antibacterial agents such as triclosan in consumer products has not been studied extensively. No data exist to support their efficacy when used in such products or any need for them, but increasing data now suggest growing acquired resistance to these commonly used antimicrobial agents."

"The use of common antimicrobials for which acquired resistance has been demonstrated in bacteria as ingredients in consumer products should be discontinued, unless data emerge to conclusively show that such resistance has no impact on public health and that such products are effective at preventing infection."

California Medical Association

Resolution on Triclosan, 10/2011



- **RESOLVED:** That CMA recognize the toxicity and potential adverse health and environmental effects of Triclosan-containing products and endorse efforts to eliminate this chemical from consumer and health care products; and be it further
- **RESOLVED:** That CMA encourage the Food and Drug Administration to finalize the antimicrobial monograph first drafted in 1978 and updated in 1994, which found evidence for the safety and effectiveness of only alcohol and iodine-based topical products in health care use; and be it further
- **RESOLVED:** That CMA encourage the education of members on the issue of the importance of proper hand hygiene and the preferential use of plain soap and water or alcohol-based hand sanitizers in health care settings, consistent with the recommendations of the Centers for Disease Control; and be it further

Hospital initiatives



- Kaiser Permanente
 - Eliminated the use of triclosan hand soaps in all facilities, public and patient care areas.
 - Also doesn't recommend the use of antimicrobial impregnated fabrics, paints, carpets or building materials because of unproven effectiveness and higher costs

Consumer advice on avoiding antimicrobials



- Use plain soap and water
- Alcohol –based hand sanitizers
- Avoid buying other products impregnated with antimicrobials
- Read labels
- Organic food ?

Local Initiatives



Discontinued purchasing of antibacterial (triclosan) soaps

- Palo Alto, CA (2006)
- East Bay Municipal Utility District (2007)
- San Jose, CA (2008)
- Minnesota – All state agencies will eliminate purchasing of hand soaps, dish and laundry cleaning products (June, 2013)
- UT-Austin campus ban on triclosan soaps

Country Initiatives

- Canada declared triclosan “toxic to the environment”
- March 30, 2012
- EU limits allowed in personal care products and ban on use in food contact products.

Norway, Denmark, Sweden, Finland – issued consumer advisories.

Norway instituted a ban “No necessary function in most products”

Germany - “use should be restricted to the absolutely necessary minimum”

Japan – restricted amount allowed in consumer products

Resources



Natural Resources Defense Council
www.nrdc.org

NRDC fact sheet on triclosan
Available for download at:

www.nrdc.org/health/files/antimicrobials.pdf

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