

FS	BIODESIGN INSTITUTE
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Presenter Disclosures

Rolf Halden, PhD, PE

The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months:

I am listed as an inventor on pending patent applications filed on behalf of Arizona State University for methods and systems suitable for removing antimicrobials from contaminanted environments.

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Context

Some materials from this presentation previously were presented at:

(1) Halden, RU: Congressional Briefing on Triclosan, Washington, DC, February 17, 2011

(2) Halden, RU: 2011 Dr. Leroy E. Burney Lecture at the Johns Hopkins University on Johns Hopkins Bloomberg School of Public Health, March 3, 2011

(3) Halden, RU: EPA Emerging Contaminant Group, Broadcasted on April 6, 2011

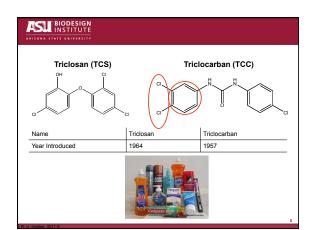


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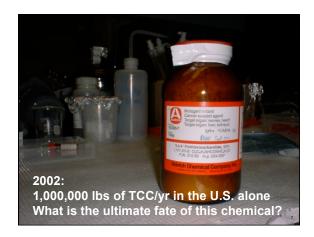
Outline

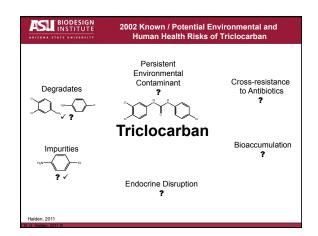
- A Case Study of An Antimicrobial's Life Cycle
- Nationwide Data on Antimicrobials
- Regulatory Challenges & Opportunities
- Conclusions



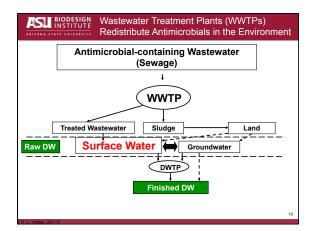


ASIL BIODESIGN INSTITUTE Persistent Ar	ntimicrobials
CI CI R ₂	A
$ \begin{array}{c} \textbf{Triclosan} (\textbf{TCS}) \\ \textbf{NCC}, \textbf{Carbanilide} (R_1 \! = \! H; R_2 \! = \! H; R_3 \! = \! H; R_4 \! = \! H) \\ \textbf{DCC}, \textbf{Dichlorocarbanilide} (R_1 \! = \! CI; R_2 \! = \! H; R_3 \! = \! CI; R_4 \! = \! H) \\ \textbf{TCC}, \textbf{Tricklorocarbanilide} (R_3 \! = \! CI; R_3 \! = \! CI; R_3 \! = \! CI; R_4 \! = \! H) \\ \textbf{TetCC}, \textbf{Tetrachlorocarbanilide}, (R_3 \! = \! CI; R_3 \! = \! CI; R_4 \! = \! CI; R_3 \! = \! CI; R_4 \! = \! CI) \\ \textbf{TetCC}, \textbf{Tetrachlorocarbanilide}, $	
CI CI CI CI Banned in 1972	
Hexachlorophene (HC	CP)
Heidle	er & Halden, J. Environ. Monit. 11:2207-2215 (2009) 6

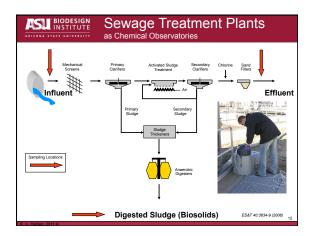


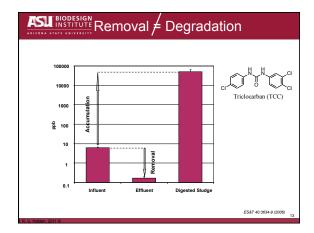


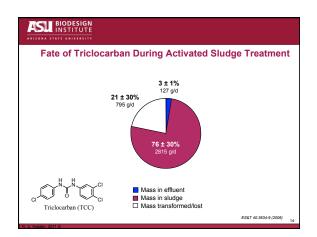
AST BIODESIGN INSTITUTE ARIZONA STATE UNIVERSITY	2011 Known / Potential En Human Health Risks of	
Degradates	Persistent Environmental Contaminant	Cross-resistance to Antibiotics
Impurities		Bioaccumulation ✓
√	Endocrine Disruption	
Halden, 2011		





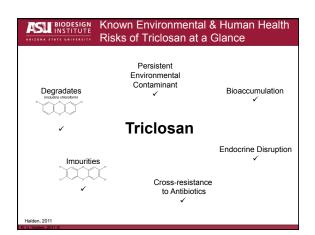


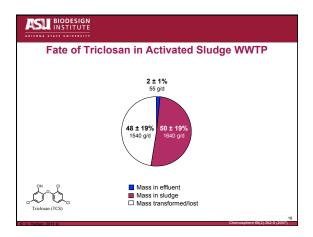


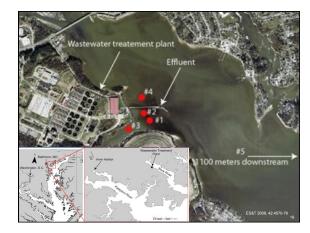


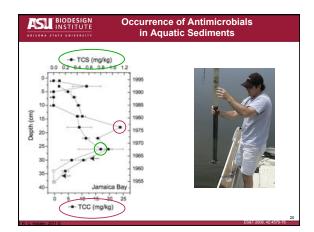






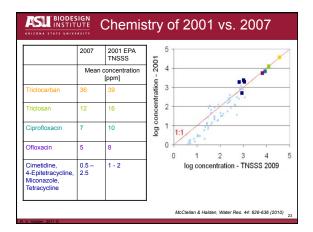


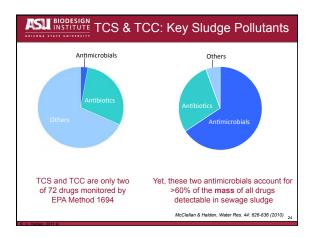




ASI BIODESIGN INSTITUTE
Nationwide Assessment of Pharmaceuticals and Personal Care Products in U.S. Biosolids Collected by the U.S. EPA in 2001
Kristin McClellan, Rolf U. Halden Ira A. Fulton School of Engineering The Biodesign Institute at Arizona State University
72 Target Compounds 94 Wastewater Treatment Plants 24 U.S. States
McClellan & Halden, Water Res. 44: 626-636 (2010) 21

ASSU BIODESIGN INSTITUTE	Study approach
To PPCPs Antimicrobials Antibiotics OTC drugs HPLC MS/MS EPA method 1694	
	McClellan & Halden, Water Res. 44: 626-636 (2010)





ASU BIODESIGN **Contaminated Land** Approximately 92,000-114,000 lbs/yr of Triclosan and 264,000- 330,000 lbs/yr of **Triclocarban** are applied inadvertantly on U.S. agricultural land as a result of sewage sludge disposal

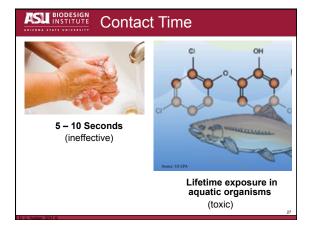
This presents a pathway for contamination of food with antimicrobials and drugresistant microbes

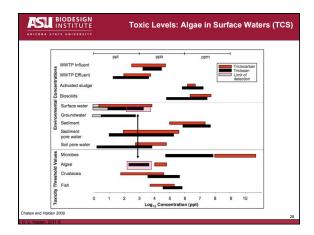
McClellan & Halden, Water Res. 44: 626-636 (2010)

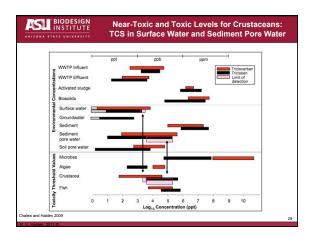
ASJ BIODESIGN Other Known Impacts

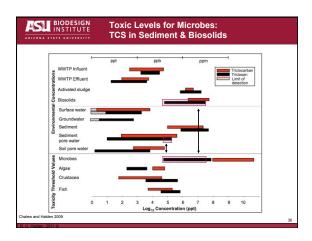
- Bioaccumulation
 - Algae
 - Crustacea
 - Fish
 - Dolphins
 - Worms
- Endocrine disruption
- Other Impacts
 - Behavioral changes
 - Immuno-toxic effects
 - Growth impairment

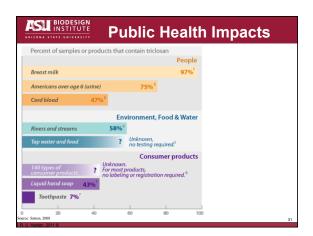




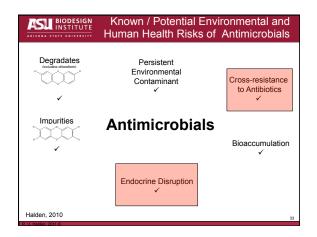








ASI INSTITUTE Timeline of TCS Regulation by FDA		
1974	Tentative Final Monograph (TFM)	
	Evidence lacking for Triclosan safety and effectiveness	
1978	g ,	
1370	<u> </u>	
4004	Claims may be misleading to consumers	
1994	Removal of antibacterial soaps from drug category	
	Proliferation is not a problem	
1997	Recommended surveillance system for drug resistance	
	•	
2005	FDA meeting to finalize "tentative final monograph"	
2000	1 B/ (meeting to initialize tentative initial monograph	
0044	Occupants of the Coffee of TOO (Helder Atally Afficially all)	
2011	Congressional briefing on TCS (Halden, Aiello, Vikesland)	
	No proven benefit / Known human health & env. risks	
Now	After 37 years, TFM still not finalized Modified from: AE Aiello, 2011	
I	32	



ASI BIODESIGN Summary

- sterilizing our homes and bodies is the fiction of marketing
- proper hygiene is essential but can be attained by using regular soap and water, thereby avoiding environmental pollution
- most antimicriobial products are ineffective for non-clinical uses (FDA Expert Panel, 2005)
- unwarranted use of antimicrobial products can pose risks to humans and the environment

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Conclusions

- · Antimicrobials persist in the environment
- · Ubiquitous contamination threatens some biota
- · Current use of antimicrobials is unsustainable
- Cutting back on antimicrobials is feasible (e.g., hexachlorophene)
- Opportunity: removal of TCS/TCC from market would reduce burden of PPCPs in agricultural soils by >60%
- · Antimicrobial drug resistance needs more study
- Endocrine disruption and multi-drug resistance drive risk
- Antimicrobials need to be managed/regulated more effectively

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NIEHS 1R01ES015445 Johns Hopkins Center for a Livable Future







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