

Applying the Precautionary Principle to Consumer Household Cleaning Product Design

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Agenda

- Seventh Generation
- Precautionary Principle
 - Definition, Domains, and Criticisms
- Application in Product Development
 - Disinfectant Active Ingredients
- Summary
- Questions



Seventh Generation

“In our every deliberation we must consider the impact of our decisions on the next seven generations.”

- From the Great Law of the Iroquois Confederacy



Precautionary Principle

"When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."

-- Wingspread Statement on the Precautionary Principle, Jan. 1998



Precautionary Principle

Central Components

- Taking preventive action in the face of uncertainty
- Shifting burden of proof to proponents of an activity
- Exploring a wide range of alternatives to possible harmful actions
- Increasing public participation in decision making

Points of Opposition

- Current regulatory procedures are precautionary
- Not scientifically sound because it advocates decision making without adequate scientific justification
- Stifles innovation by requiring proof of safety before new technologies can be introduced

The Precautionary Principle in Household Cleaner Product Development: Ingredient Selection

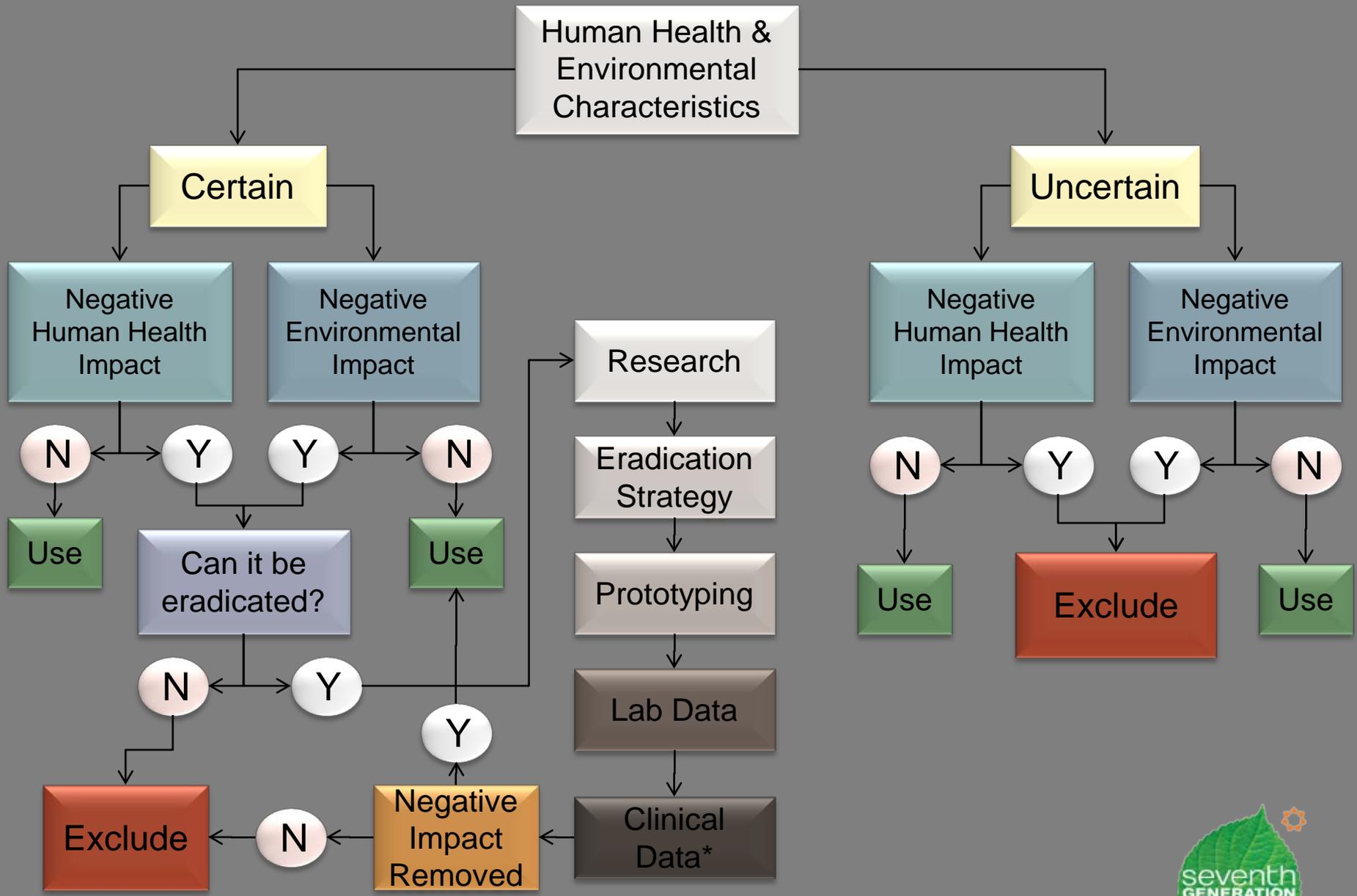
Human Health

- **Acute Toxicity**
 - Ocular
 - Dermal
 - Oral
 - Inhalation
- **Chronic Toxicity**
 - Carcinogenicity
 - Neurotoxicity
 - Developmental / Reproductive Toxicity
 - Hormone Mimicry
 - Mutagenicity
 - Sensitization Potential

Environment

- Volatile Organic Compounds
- Ozone Depletion
- Indoor Air Quality
- Eutrophication
- Biodegradation
- Toxicity in aquatic and terrestrial wildlife
- Animal Testing
- Animal Ingredients
- Antimicrobial Resistance
- Resource Renewability





*For human health issues only



How do we
manage
scientific
uncertainty
with
antimicrobials?



Mounting Evidence Links Conventional Disinfectants to Human Health and Environmental Issues

Human Health Effects:

- Burge PS, Richardson MN. Occupational asthma due to indirect exposure to lauryl dimethyl benzyl ammonium chloride used in a floor cleaner. *Thorax*. 1994;49:842-843.
- Purohit A, et.al. Quaternary ammonium compounds and occupational asthma. *International Archives of Occupational and Environmental Health*. 2000;73:423-427.
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- Leroyer C, et.al. Changes in airway function and bronchial responsiveness after acute occupational exposure to chlorine leading to treatment in a first aid unit. *Occupational and Environmental Medicine*. 1998;55:356-359.
- Sherriff A, Farrow A, Golding J, Hendersen J. Frequent use of chemical household products is associated with persistent wheezing in pre-school age children. *Thorax*. 2005;60:45-49.
- Nickmilder M, Carbonnelle S, Bernard A. House cleaning with chlorine bleach and the risks of allergic and respiratory diseases in children. *Pediatric Allergy and Immunology*, 2007;18:27-35.
- Preller L, Doekes G, Heederik D, Vermeulen R, Vogelzang PF, Boleij JS. Disinfectant use as a risk factor for atopic sensitization and symptoms consistent with asthma: an epidemiological study. *European Respiratory Journal*, 1996;9:1407-13.

Environmental Effects:

- GAZE, W. H., et.al. (2005) Incidence of class 1 integrons in a quaternary ammonium compound-polluted environment. *Antimicrobial Agents and Chemotherapy*, 49 1802-1807.
- FRY, M. (2005) Reproductive effects in birds exposed to pesticides and industrial chemicals. *Environmental Health Perspectives*, 103, 165-171.
- ODABASI, M. (2008) Halogenated volatile organic compounds from the use of chlorine-bleach-containing household products. *Environmental Science & Technology*, 42, 1445-51.
- RUSSELL, A. D., et.al. (1998) Possible link between bacterial resistance and use of antibiotics and biocides. *Antimicrobial Agents and Chemotherapy*, 42, 2151.
- SUNDHEIM, G., et.al. (1998) Bacterial resistance to disinfectants containing quaternary ammonium compounds. *International Biodeterioration and Biodegradation*, 41, 235-239.
- FISS, E. M., et.al. (2007) Formation of chloroform and other chlorinated byproducts by chlorination of triclosan-containing antibacterial products. *Environmental Science & Technology*, 41, 2387-2394.
- LEVY, S. B. (2001) Antibacterial Household Products: Cause for Concern. *Emerging Infectious Diseases*, 7, 512-515.
- FAIR, P. A., et.al. (2009) Occurrence of triclosan in plasma of wild Atlantic bottlenose dolphins (*Tursiops truncatus*) and in their environment. *Environmental Pollution*, 157, 2248-2254.



Common Disinfectant Actives

- Sodium Hypochlorite
- Quaternary Ammonium Compounds
- Triclosan



Quaternary Ammonium Compounds

What is Certain

- Broad spectrum antimicrobial efficacy
- Biochemical mechanism of action
- Synthetic (petroleum-based)
- Not VOCs
- Quick primary biodegradation, remaining molecules are difficult to destroy
- Variable aquatic toxicity

What is Uncertain

- Respiratory sensitization & asthma in formulation
- Dermal contact allergy & irritation in formulation
- Potential to cause microbial resistance
- Persistence in the environment



Sodium Hypochlorite

What is Certain:

- Sterilant – able to annihilate all microorganisms including spores
- Physical mechanism of action
- Made from renewable materials
- Reacts with ozone to produce halogenated VOCs
- All major POPs are chlorinated
- Toxic to aquatic and terrestrial wildlife
- Acute respiratory irritant sometimes exacerbating RADS
- Irritating to many human tissues

What is Uncertain

- Carcinogenicity of secondary reaction products
- Chronic respiratory effects at low exposure levels
- Contribution to chlorinated chemistries with known negative health and environmental impacts



Triclosan

What is Certain

- Broad spectrum antimicrobial efficacy
- Biochemical mechanism of action
- Synthetic, chlorinated antimicrobial
- Forms dioxin-like compounds when exposed to sunlight
- Persists in the environment

What is Uncertain

- Long-term effects of photochemical degradation on human health and the environment
- Potential for endocrine disruption
- Potential to cause microbial resistance



Traditional active ingredients have significant amounts of uncertainty

Certainties & Uncertainties	Acute Toxicity	Chronic Toxicity	Air Quality	Water Quality	Wildlife Toxicity	Persistence	Animal Use	Resistance	Resources
QACs									
Respiratory sensitization & asthma	?	?							
Dermal contact allergy and irritation	?	?							
Potential to cause microbial resistance (biochemical MOA)								?	
Persistence in the environment			?	?	?	?			
Variable aquatic toxicity					?				
Synthetic (petroleum-based)									✓
Sodium Hypochlorite									
Contribution to chlorinated chemistries	?	?	?	?	?				
Chronic respiratory effects at low exposure levels		?							
Carcinogenicity of secondary reaction products		?	?						
Reacts with ozone to produce halogenated VOCs	✓	✓	✓						
Acute respiratory irritant sometimes exacerbating RADS	✓								
Irritating to many human tissues	✓								
Toxic to aquatic and terrestrial wildlife					✓				
All major POPs are chlorinated						✓			
Triclosan									
Long-term effects of photochemical degradation on human health and the environment	?	?	?	?	?				
Potential for endocrine disruption		?			?				
Potential to cause microbial resistance (biochemical MOA)								?	
Synthetic, chlorinated antimicrobial									✓
Forms dioxin-like compounds when exposed to sunlight	✓	✓			✓				
Persists in the environment						✓			

✓: Certainty
?: Uncertainty



Thymol

What is Certain

- Broad Spectrum antimicrobial efficacy
- Physical mechanism of action
- Botanical and renewable
- Essential oils are irritating to eyes and skin at full concentration
- Biodegradable into non-toxic by-products
- Does not contain allergens

What is Uncertain

- Not Applicable – Thymol has been a part of the human diet and folkloric medical traditions for 1000s of years.



Review of Irritation Potential

Certainties & Uncertainties	Acute Toxicity	Chronic Toxicity	Air Quality	Water Quality	Wildlife Toxicity	Persistence	Animal Use	Resistance	Resources
Thymol									
Irritating to eyes and skin at full concentration	✓								

- Literature review of ocular and dermal irritation including federal regulations
- Determination of potentially non-irritating concentrations
- Formula prototype generation
- Laboratory and clinical data generation with formulated product prototypes



Summary

- The precautionary principle is an effective tool for selecting safe ingredients to develop consumer household products
- It is important to consider attributes of the neat raw material AND formulated product
- The precautionary principle does not stifle innovation



Thank You!

