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Major article

Application of quantitative microbial risk assessment for selection of microbial reduction targets for hard surface disinfectants

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Background: This quantitative microbial risk assessment (QMRA) included problem formulation for fomites and hazard identification for 7 microorganisms, including pathogenic *Escherichia coli* and *E coli* 0157:H7, *Listeria monocytogenes*, norovirus, *Pseudomonas* spp, *Salmonella* spp, and *Staphylococcus aureus*. The goal was to address a risk-based process for choosing the $\log_{10}$ reduction recommendations, in contrast to the current US Environmental Protection Agency requirements.

Method: For each microbe evaluated, the QMRA model included specific dose-response models, occurrence determination of aerobic bacteria and specific organisms on fomites, exposure assessment, risk characterization, and risk reduction. Risk estimates were determined for a simple scenario using a single touch of a contaminated surface and self-inoculation. A comparative analysis of $\log_{10}$ reductions, as suggested by the US Environmental Protection Agency, and the risks based on this QMRA approach was also undertaken.

Results: The literature review and meta-analysis showed that aerobic bacteria were the most commonly studied on fomites, averaging 100 colony-forming units (CFU)/cm^2. *Pseudomonas aeruginosa* was found at a level of 3.3×10^{-1} CFU/cm^2; methicillin-resistant *S aureus* (MRSA), at 6.4×10^{-1} CFU/cm^2. Risk estimates per contact event ranged from a high of 10^{-3} for norovirus to a low of 10^{-9} for *S aureus*.

Conclusion: This QMRA analysis suggests that a reduction in bacterial numbers on a fomite by 99% (2 logs) most often will reduce the risk of infection from a single contact to less than 1 in 1 million.

The currently available test methods for assessing the efficacy of hard surface cleaners were developed without the advantage of knowing the numbers and types of organisms that can be detected on fomites using today's microbiological tools. The US Environmental Protection Agency (EPA) has published efficacy requirements for the concentrations of test organisms required in disinfection testing protocols to achieve nondetection or targeted log reductions without a well-articulated risk-based reduction rationale supported by data. The application of quantitative microbial risk assessment (QMRA) frameworks and models over the last several decades have provided approaches for the control of infectious agents in water and food. For example, QMRA has been used to assess the treatment technology goals for reducing virus and parasites to acceptable levels in drinking water[1] and to determine risk criteria for pathogens, such as *Salmonella* spp, in certain foods.[2] QMRA also provides a mechanism for developing technically informed disinfection goals for surface hygiene and safety.[3,4]

Fomites have been recognized as important in the spread of infectious disease, particularly through fomite–hand interactions and are common concerns in environments of high contacts (touches) with such pathogens as norovirus, influenza, and rotavirus, as well as and methicillin-resistant *Staphylococcus aureus* (MRSA).[5-14] Fomites have been associated with infectious disease outbreaks in such venues as cruise ships, restaurants and nursing homes,[15] schools,[16,17] daycare centers,[18] and gyms.[19,20]

Cleaning, sanitation, and disinfection have different goals when treating surfaces for the removal of dirt and specific requirements for controlling microorganisms. The US EPA Pesticide Program has defined the products used for these purposes in 5 descriptive categories: nonfood contact surface sanitizers, limited disinfectants, general/broad-spectrum disinfectants, medical environment

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disinfectants, and food contact surface sanitizers (nonhalide products). Table 1 describes the EPA requirements and associated surrogate organisms for use in testing for each of these categories, including *S aureus*, *Klebsiella pneumonia*, *Enterobacter aerogenes*, *Salmonella enterica* ser. *choleraesuis*, *Pseudomonas aeruginosa*, and/or *Escherichia coli*.

The present study had 2 goals: (1) to provide background data on microbial surface contamination reported in studies for households, restaurants, work offices, hospitals, schools and daycare centers, and (2) to provide a data-based assessment of the risk associated with enteric and skin pathogens via exposure to contaminated fomites and the levels of risk reduction achieved by treatment within the 5 EPA product categories. Seven pathogenic organisms with dose-response datasets were selected for developing a QMRA to examine the risk reduction from sanitation and disinfection of fomites: pathogenic *E coli*, *E coli* 0157:H7, *Listeria* spp, norovirus, *Pseudomonas* spp, *Salmonella* spp, and *S aureus*.

Problem formulation and hazard identification

Fomites refer to inanimate structural materials found mostly in indoor environments (ie, buildings) that are part of our everyday lives. Examples include walls, floors, chairs, tables, books, toys, mobile phones, computer keyboards, door handles, and bedrails. Fomites also include surfaces used for food preparation, such as countertops and sinks.

Two groups of hazards and associated exposure pathways involving fomites were evaluated in the present study. The first group comprised enteric bacteria and viruses that spread via fecal-hand-fomite-hand-mouth pathways, including pathogenic *E coli*, *E coli* O157:H7, *Listeria*, *Salmonella*, and norovirus. Norovirus also can be found in vomitus, and *Listeria*, *E coli*, and *Salmonella* can regrow in foods and be shed in the feces of animals (eg, pets). The second group were skin-borne and eye infections associated with staphylococci and *Pseudomonas*, respectively, which spread by hands to skin or eyes from sources including natural flora of the skin, nasal passages, pets, water, soil and foods.

E coli, a gram-negative bacterium, is one of the most diverse groups of organisms that commonly inhabit the intestines of warm-blooded animals. These bacteria serve as fecal indicators, because they are always present in feces in fairly large numbers. There are 5 classes of pathogenic *E coli* associated with diarrhea, including enterotoxigenic (ETEC), enteroinvasive (EIEC), a subgroup of Shiga toxin–producing *E coli* known as enterohemorrhagic (EHEC), enteropathogenic (EPEC), and enteroaggregative (EAEC). *E coli* O157:H7, a member of the EHEC group,[21] causes hemorrhagic colitis (inflammation of the intestinal wall), and the toxins cause damage to endothelial cells in the kidneys, thereby inhibiting the organs' ability to function.[22] Young children and elderly adults can develop hemolytic uremic syndrome (HUS) as a result of exposure to *E coli* O157:H7, a condition that can lead to serious kidney damage and even death.[23]

Listeria monocytogenes is receiving much attention owing to the increasing numbers of food-associated outbreaks. One such outbreak was associated with cantaloupe in 2011.[24] A total of 146 persons from 28 states were infected with *L monocytogenes*, and 30 deaths were reported. One woman who was pregnant at the time of illness had a miscarriage. According to the Centers for Disease Control and Prevention (CDC), 3-4 food-borne outbreaks occur and approximately 800 cases are reported each year in the United States. Common high-risk foods include deli meats, hot dogs, and Mexican-style soft cheeses made with unpasteurized milk. Sprouts were associated with an outbreak in 2009, and in 2010 an outbreak was caused by celery, even though produce is not a common food associated with *Listeria*.[24] One of the main risk factors for *Listeria* is

Table 1
US EPA product categories and goals for microbial reductions associated with sanitizers and disinfectants* (gram stain + or −)

Category	Nonfood contact surface sanitizer	Limited disinfectant	General/broad-spectrum disinfectant	Medical environment disinfectant	Food contact surface sanitizer (nonhalide products)
Claims allowed	Sanitizer; kills 99.9% (3 log 10) germs Kills [organisms tested]	Limited disinfectant against [organism] Kills [organism tested]	Disinfectant, kills germs Kills [organisms tested]	Disinfectant antibacterial; kills germs Kills [organisms tested]	Sanitizer; kills 99.999% (5 $\log_{10}$) of germs on food contact surfaces Kills [organism tested]
Test method (product can be tested neat or dilute)	Sanitizer test for nonfood contact surfaces	Use dilution test (liquids) or germicidal spray products test	Use dilution test (liquids) or germicidal spray products test	Use dilution test (liquids) or germicidal spray products test	Germicidal and detergent sanitizer test
Performance standard	99.9% (3 log 10) reduction in 5 min	100% kill* in 10 min	100% kill* in 10 min	100% kill* in 10 min	99.999% (5 log 10) reduction in 30 s
Target organisms* (to these can be added claims against odor-causing bacteria (eg, *E coli*, *Proteus mirabilis*))	Two organisms: *S aureus* (+) and *K pneumoniae* (−) or *Enterobacter aerogenes* (−)	One organism: *Salmonella choleraesuis* (−) or *S aureus* (+)	Two organisms: *S choleraesuis* (−) and *S aureus* (+)	Three organisms: *S choleraesuis* (−), *S aureus* (+), and *P aeruginosa* (−)	Two organisms: *E coli* (−) and *S aureus* (+)

For *Salmonella*, the 100% kill of a minimum target of 10^4 (4 log 10).
For *Staphylococcus*, the 100% kill of a minimum target of 10^5 (5 log 10).
*100% kill of up to a targeted concentration of 10^7 (7 log 10).