Risk-Based Review of California's Water-Recycling Criteria for Agricultural Irrigation

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Abstract: California currently recycles treated wastewater at a volume of approximately 8.0×10^8 m³ of water per year, with a potential to recycle an additional 1.9×10^9 m³ per year. A key challenge in promoting the expansion of water recycling for agricultural purposes was addressing the perceived concern about whether recycled water produced in conformance with California law is protective of public health. The California Department of Public Health (CDPH) established an expert panel to consider the concern. The panel found, based on quantitative microbial risk assessment (QMRA), that the annualized median risks of infection for full tertiary treatment ranges from 10^{-8} to 10^{-4} (for human enteric viruses *Cryptosporidium parvum* and *Giardia lamblia*, and *Escherichia coli* O157:H7) based on the assumption of daily exposure. The panel found that risk estimates are consistent with previous CDPH estimates and concluded that current agricultural water recycling regulations do not measurably increase public health risk. **DOI:** 10.1061/(ASCE)EE.1943-7870.0000833. © 2014 American Society of Civil Engineers.

Author keywords: Microbial; Risk; Assessment; Water; Recycling.

Introduction

Background and Purpose

The State of California's water quality standards and treatment reliability criteria for water recycling are contained in the California Department of Public Health's (CDPH's) Water Recycling Criteria (Title 22, Division 4, Chapter 3, California Code of Regulations). Because of adherence to these criteria, the use of recycled water for agricultural

Note. This manuscript was submitted on August 30, 2013; approved on March 1, 2014; published online on April 18, 2014. Discussion period open until September 18, 2014; separate discussions must be submitted for individual papers. This paper is part of the *Journal of Environmental Engineering*, © ASCE, ISSN 0733-9372/04014015(10)/\$25.00.

food crop irrigation has a history of safe use (i.e., no evidence of outbreaks attributable to this use, or of increased cases of enteric disease) in California. However, improved knowledge of wastewater treatment effectiveness, changes in agricultural practices, and increased knowledge of the behavior of pathogens and disease have prompted a reevaluation of California's Water Recycling Criteria. Therefore, CDPH convened an expert panel "to consider whether recycled water produced in conformance with California's Water Recycling Criteria is sufficiently protective of public health for agricultural food crop irrigation" (Cooper et al. 2012). The criteria vary according to the type of agricultural irrigation. For example, for irrigation of food crops eaten raw where there is direct contact between the recycled water and edible portion of the crop, the criteria require tertiary treatment (secondary treatment followed by filtration to achieve a turbidity of ≤2 NTU), and disinfection to produce a 7-day median total coliform level of ≤2.2/100 mL in the recycled water with a product of the total chlorine residual concentration and the model contact time (i.e., CT value) of not less than 450 mg-min per liter.

The scope of the panel's review was limited to the irrigation of agricultural food crops and excludes urban and residential irrigation, irrigation of nonfood agricultural crops (such as turf and fodder, seed, fiber, and ornamental crops), and all nonirrigation uses. Further, the review was limited to exposure to waterborne pathogens of concern from the irrigation of a wide variety of food crops requiring different recycled water qualities, as noted subsequently.

Administered by the National Water Research Institute (NWRI), the NWRI Independent Advisory Panel (Panel) reviewed a number of topics such as available risk assessment information, including exposure assessment and hazard characterization; filtration requirements, including the turbidity performance standard, acceptable filter designs, filter loading rate, and treatment optimization; disinfection requirements, including the coliform performance standard, CT value required for chlorination, and log reduction goal for virus and protozoan parasites (*Cryptosporidium* and *Giardia*); irrigation practice assumptions and other best management practices; treatment reliability requirements; monitoring requirements; and the role of multibarrier treatment.

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While the Panel was tasked with addressing a number of questions (Cooper et al. 2012), the purpose of this paper is to present the results of the Panel's quantitative microbial risk assessment (QMRA).

California Water Reuse

For nearly a century, recycled water has been used intentionally as a nonpotable water supply source in California. The implementation of reclamation projects has increased significantly over the years, even in the face of regulatory, economic, and social constraints. At present, estimates indicate that only approximately 8 to 10% of municipal wastewater is recycled in planned reuse projects.

In 1989, the reuse of municipal wastewater in California was estimated at 400×10^6 m³/year. More recent SWRCB data indicate that, during 2009, approximately 862×10^6 m³/year of recycled water was used (SWRCB 2012). The statewide survey indicates that the top three applications are for agricultural uses (37%), landscape irrigation (17%), and groundwater recharge and seawater intrusion barrier uses (19%). Agricultural reuse in California represents the largest percentage of the total recycled water used in the state—roughly 319×10^6 m³/year. Agricultural reuse in California can be further divided into six main categories (as percentage of the 37%) (U.S. EPA 2004):

- Mixed (approximately 16%);
- Harvested feed, fiber, and seed (approximately 14% of total agricultural reuse);
- Pasture (approximately 4% of total agricultural reuse);
- Orchards and vineyards (approximately 1% of total agricultural reuse);
- Food crops (approximately 1% of total agricultural reuse); and
- Nursery and sod (approximately 1% of total agricultural reuse). Estimates regarding future overall recycling indicate that California has the potential to recycle an additional 1.9 × 10⁹ m³/year of water by the year 2030 (D. Smith, personal communication, 2010). While current estimates of reuse for food crop production is on the order of 2%, the Panel assumed for analysis purposes that estimated food crop use could increase to 8%.

Material and Methods

QMRA involves evaluating the likelihood that an adverse health effect may result from human exposure to one or more pathogens. The Panel's literature review to establish the set of pathogens examined in its assessment is described first, followed by the Panel's model and risk calculation approach.

Pathogens of Public Health Concern for Agricultural Reuse on Food Crops

The Panel considered the following factors relevant to infectious disease from human exposure to raw (as well as treated) wastewater: (1) for waterborne illness or disease to occur, an agent of disease (pathogen) must be present; (2) the agent must be present in sufficient concentration to produce disease (dose); and (3) a susceptible host must come into contact with the dose in a manner that results in infection or disease (Cooper et al. 1986; Cooper 1991).

Although a wide range of pathogens have been identified in raw wastewater, relatively few types of pathogens appear to be responsible for the majority of the waterborne illnesses caused by pathogens of wastewater origin (Mead et al. 1999). The pathogens of public health concern, based on foodborne disease in the United States, were identified by the Centers for Disease Control (CDC) (Mead et al. 1999). Noroviruses (provisionally known as

Norwalk-like viruses) have been reported to account for 23 million illnesses each year, of which 60% are estimated to be nonfoodborne. Rotavirus accounts for 3.9 million illnesses each year, of which 99% are nonfoodborne (Mead et al. 1999). With this background, it follows that many of these pathogens find their way into domestic wastewater.

Review of the CDC research data indicates that 85–90% of all nonfoodborne cases (i.e., cases related to other routes of transmission such as waterborne) in the United States are caused by viral pathogens (i.e., enteric viruses). The relative importance of viral pathogens in waterborne transmission of disease is supported by data from the World Health Organization (WHO) (1999) and by research conducted over the last 20 years on exposure to waterborne pathogens through recreational activities (Cabelli 1983; Fankhauser et al. 1998; Levine and Stephenson 1990; Palmateer et al. 1991; Sobsey et al. 1995; Wade et al. 2003).

Based on the previous discussion of possible pathogens of concern, pathogens known to be present in wastewater, the CDC's estimated disease burden in the United States, and those pathogens where water recycling plant performance and exposure data may exist, the following is the Panel's list of pathogens of public health concern:

- Human enteric viruses as estimated by enterovirus occurrence in recycled water and rotavirus dose response;
- Protozoa as estimated by Cryptosporidium parvum and Giardia lamblia; and
- Bacteria as estimated by E. coli O157:H7.

In addition, other organisms of interest include adenovirus and noroviruses. However, for reasons noted subsequently, these pathogens were not investigated as part of this analysis:

- Adenoviruses were discussed with the Panel, but adenovirus
 data were ultimately not analyzed by the Panel because the existing dose-response data and mathematical relationship (Couch
 et al. 1966; Crabtree et al. 1997) apply to inhalation and, thus,
 may not be applicable to the exposure routes considered.
- Norovirus was not explicitly analyzed because a comparison of the dose-response relationship for norovirus (Teunis et al. 2008) with rotavirus indicates that use of the rotavirus dose-response was more conservative (i.e., health protective) with respect to estimating the risks from enteric viruses.

Quantitative Microbial Risk Assessment

A static model (National Research Council 1983) was chosen for the QMRA. This model is commonly used as a generic framework for conducting microbial risk assessments of waterborne and foodborne pathogens (Crabtree et al. 1997; Farber et al. 1996; Haas et al. 1999; Sanaa et al. 2000; Voysey and Brown 2000). Assessments using a static model typically focus on estimating the probability of infection or disease to an individual as a result of a single exposure event. These assessments generally assume that multiple or recurring exposures constitute independent events with identical distributions of pathogens of concern (Regli et al. 1991). Secondary transmission (e.g., person-to-person transmission) and immunity are assumed negligible or that they effectively cancel each other out.

In the static model, it is assumed that the population may be categorized into two epidemiological states: a susceptible state and an infected or diseased state. Susceptible individuals are exposed to the pathogen of interest and move into the infected or diseased state with a probability that is governed by the dose of pathogen to which they are exposed and the infectivity of the pathogen. A schematic diagram of the static model is presented in Fig. 1 (Colford et al. 2003). An important part of characterizing

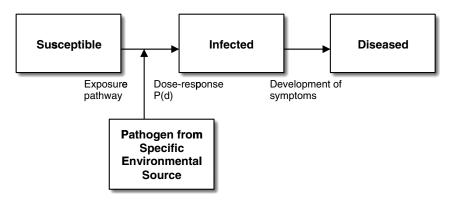


Fig. 1. Static risk assessment conceptual model

the susceptible population is considering the highly susceptible subpopulations. While the Panel recognized this important factor, current data do not allow for a more rigorous quantitative assessment (Parkin et al. 2003).

Although static models typically focus on estimating the risk per exposure event, in cases where the risk is expressed per day, the risk may be annualized as

$$P = 1 - [1-Probinf(d)]^n$$

where P = probability of being infected at least once during the year; Probinf(d) = probability of being infected for a given daily dose d; and the number of days of exposure in a year is n.

The Panel's investigation relied on use of a static model employing Monte Carlo simulations in a comparative screening level risk characterization and is consistent with the literature in the field describing conditions in which the use of the static model is appropriate (Cooper et al. 1986; Haas 1983; Haas et al. 1999; Soller et al. 2004). The general approach for this assessment, illustrated in Fig. 2, was to utilize existing data and QMRA methods to derive a matrix of relative risks based on combinations of pathogens representing those of greatest public health concern, treatment processes that are representative of those currently used to produce recycled water used for irrigation of food crops, and relevant exposure routes based on food crop irrigation.

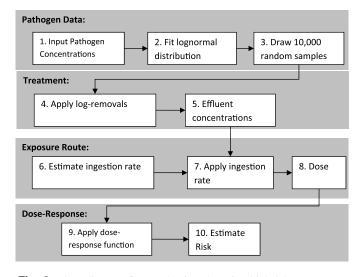


Fig. 2. Flow diagram for conducting the microbial risk assessment

Pathogen Concentrations in Untreated Wastewater and Recycled Waters Assumptions

Data from the WateReuse literature review (Olivieri et al. 2007) and the results a Water Environment Research Foundation (WERF) report (Rose et al. 2004) were the key sources of input data in this characterization of the Panel's QMRA. In the investigation by Rose et al. (2004), six full-scale wastewater treatment and reclamation facilities in Arizona, California, and Florida were each monitored over a 1-year period for a variety of pathogens and indicator organisms (Table 1). For the QMRA, it was assumed that the six wastewater treatment facilities were representative of the types of reclamation facilities that are currently employed in California. By comparison, of the WateReuse literature review with the WERF data, the Panel concluded that the WERF data provide a useful representation of the concentrations of enteroviruses, *Cryptosporidium* spp., and *Giardia* spp. in both raw wastewater and secondary effluent.

Data on *E. coli* O157:H7 concentrations in raw wastewater and secondary effluent were extremely limited. Quantitative data for *E. coli* O157:H7 in raw wastewater have been reported by three research teams (Garcia-Aljaro et al. 2005; Heijnen and Medema 2006; Muniesa et al. 2006). A summary of those data is provided in Table 2. The results reported by Heijnen and Medema (2006) were used for the QMRA.

To rigorously account for the variability observed in pathogen concentrations in raw wastewater and secondary effluent, the pathogen concentration data summarized previously were fit to lognormal probability distributions using maximum likelihood estimation (MLE) (Ott 1995). The lognormal distribution is a commonly used distributional form for environmental data fitting for concentrations of microorganisms in water (U.S. EPA 1991). From this lognormal distribution, 10,000 random samples were generated to represent a likely distribution of concentrations, which was then

Table 1. Summary of Raw Wastewater Pathogen Concentration Distributions Used for Modeling

Pathogen	Distribution
Enterovirus (most probably	Lognormal (log mean 3.19,
number per liter)	log standard deviation 1.74) ^a
Giardia lamblia (cysts	Lognormal (log mean 5.66,
per liter)	log standard deviation 1.91) ^a
Cryptosporidium parvum	Lognormal (log mean 2.85,
(oocysts per liter)	log standard deviation 1.75) ^a
E. coli O157:H7	Uniform (minimum 0,
(organisms per liter)	maximum 5,000) ^b

^aBased on Rose et al. (2004) data.

^bBased on Heijnen and Medema (2006) data.

Table 2. Literature Review for *E. coli* O157:H7 Concentrations in Units per Liter

Source	Influent concentration	Notes
Heijnen and Medema (2006)	0-5,000	Two samples below detection: one at 400 and one at 5,000
Muniesa et al. (2006)	100-1,000	_
Garcia-Aljaro et al. (2005)	2×10^3	Based on eight samples, $log(colony - formingunit)/mL = 0.2$ with standard deviation = 0.2

used in subsequent calculations. Instead of the lognormal, the uniform distribution for *E. coli* O157:H7 concentrations based on Heijnen and Medema (2006) was used. This number of samples was determined to produce a smooth distribution of concentration and subsequent computed distribution of risk, from which median risk could be estimated.

The values shown in Table 3 are the expected log reductions for the corresponding combination of wastewater treatment processes matching CDPH treatment standards. For each set of simulations, 10,000 pathogen concentrations were sampled from the MLE lognormal distribution and the reduction distributions (from wastewater treatment) were subsequently multiplied. The products from these multiplications resulted in 10,000 estimated effluent concentrations (per liter). Additionally, a sensitivity analysis of treatment efficacy was performed.

Route of Exposure through Food Crop Irrigation Assumptions

Table 4 provides a summary of the agriculture reuse scenarios, consisting of treatment levels per CDPH regulations and corresponding

exposure assumptions. For Scenario I, the method used to characterize human exposure through the irrigation of food crops (e.g., lettuce) is based on that described by Hamilton et al. (2006) and is consistent with earlier work conducted by other researchers (van Ginneken and Oron 2000; Petterson et al. 2001). The exposure approach is based on the assumption that the ingestion of recycled water is the product of three distributions: the rate of consumption of crops irrigated with recycled water (g/kg-day), body mass (kg), and volume uptake (mL/g). Lettuce consumption was used as the model crop for consumption because the consumption value is health protective relative to other vegetables (U.S. EPA 2003). The consumption value for lettuce is a point estimate of 0.205 g/kg-day (U.S. EPA 2003). Body mass is estimated by a lognormal distribution with mean of 61.429 and standard deviation of 13.362 kg (U.S. EPA 1997). Volume uptake is estimated as a normal distribution with mean 0.108 and standard deviation of 0.02 mL/g (Hamilton et al. 2006).

The resultant distribution of ingestion volume; that is, the amount of irrigation water ingested via lettuce, has a median value of approximately 1.3 mL/day.

Because Scenarios II and III do not involve irrigation to the edible portion of the crop, the Panel assumed an order of magnitude less exposure than the previous lettuce case and set exposure at 0.1 mL/day. At the request of the Panel, sensitivity analyses were performed on this by also considering a lower exposure rate of 0.01 mL/day.

Environmental Decay Assumptions

The environmental decay assumptions were pathogen specific. For enterovirus, it was assumed that virus concentrations in the environment decayed exponentially with time after application to crops (i.e., decay factor = e^{-kt}) based on findings from Petterson et al. (2001) and the approach of Hamilton et al. (2006). Based on

Table 3. Summary of Pathogen Reductions through Wastewater Treatment Used in the Simulations in Units of Log Reduction

	Cryptosporidium Giardia spp. species			Rotavirus		E. coli O157:H7		
Treatment	Mean	Standard deviation	Mean	Standard deviation	Mean	Standard deviation	Mean	Standard deviation
Raw through disinfected secondary effluent	3.2	0.7	2.3	0.7	3.6	0.7	6.53	0.93
Secondary treatment through disinfected filtered effluent	1.0	0.6	0.8	0.5	1.3	0.6	4.2	1.3
Filtered secondary treatment through disinfection	0.2	0.2	0.2	0.3	0.6	0.5	2.0	1.4

Note: Normal distributions were zero truncated so that negative values were not sampled; based on a reanalysis of the Rose et al. (2004) data.

Table 4. Agriculture Reuse, Treatment, and Exposure Assumptions

Scenario	Agricultural use	Treatment	Exposure assumptions
I	Food crops (edible portion in contact with water)	Disinfected tertiary	Average daily consumption of lettuce per body weight: 0.205 g/kg-day; Body weight: lognormal distribution with mean 61.4 and standard deviation 13.4 kg; Volume of water or lettuce: zero-truncated normal distribution with mean 0.108 and standard deviation 0.02 mL/g; 7-day environmental decay ^a
II	Orchards and vineyards (no contact with edible portion of crops)	Undisinfected secondary	0.1 mL/day, assumes daily exposure and consumption; 7-day environmental decay ^a
III	Food crops (edible portion above ground—no contact)	Disinfected secondary, 2.2 most probable number/100 mL	0.1 mL/day, assumes daily exposure and consumption; 7-day environmental decay ^a

^aOver a 7-day decay period, a mean 3.3-log reduction for enterovirus, 3-log reduction for *E.coli*, and 2-log reduction for *Giardia* and *Cryptosporidium* were assumed.

Table 5. Summary of Pathogen Dose-Response Relations

Pathogen	Dose-response form and endpoint	Parameter distribution	Value(s)	Value(s)	References
Rotavirus	Hypergeometric (infection)	Point estimates	$\alpha = 0.167$	$\beta = 0.191$	Teunis and Havelaar (2000)
Cryptosporidium spp. Giardia spp.	Exponential (infection) Exponential (infection)	Uniform Point estimate	$r_{\text{lower}} = 0.04$ $r = 0.0199$	$r_{\rm upper} = 0.16$	U.S. EPA (2006) Rose et al. (1991), Teunis et al. (1996)
E. coli O157:H7	Hypergeometric (infection)	Point estimates	$\alpha = 0.08$	$\beta = 1.44$	Teunis et al. (2004)

Note: See Haas et al. (1999) for description of models and their parameters.

Petterson's study, the decay constant k was assumed to be normally distributed with a mean of $1.07~\rm day^{-1}$ and standard deviation of $0.07~\rm (zero$ -truncated). This k is conservative due to Petterson's use of *Bacillus fragilis* phage, a relatively hardy organism. Based on standard agricultural practices employed in California (Cooper et al. 2012), 7 days of environmental decay was assumed, leading to a mean 3.3-log removal due to environmental decay. Based on differences in decay among viruses, bacteria, and protozoa from the modeling study of Mara et al. (2007), it was assumed that bacteria were slightly more resistant to environmental decay than viruses. Hence, it was assumed that E.~coli experienced a 3-log removal over 7 days. For the more resistant organisms, *Giardia* and *Cryptosporidium*, a 2-log reduction due to environmental decay over the 7 days was assumed.

Dose-Response Assumptions

Pathogen-specific dose-response relationships were used to estimate the probability of infection (as opposed to symptomatic disease) for all pathogens (Table 5). For enterovirus, a rotavirus dose-response value was used as a surrogate.

Recent recreational water QMRA (Bambic et al. 2011) harmonized virus units, making consistent the concentration units from water quality testing with the units reported in dose-response studies. The study acknowledged that their water samples were analyzed by quantitative polymerase chain reaction (qPCR) for rotavirus, while the dose-response relationship of Ward et al. (1986) was in terms of doses of focus forming units (FFUs). These seemingly incompatible units were equated using a ratio of genome:FFU of ~2,000. The units used in the Panel's investigation are the most probable number (MPN), which shares greater similarity with FFU and, hence, alleviates the need for harmonization.

Results

Annualized risk estimates for the three agricultural reuse scenarios for each of the pathogens are presented in Tables 6–8. All median

Table 6. Scenario I: Tertiary Treatment Applied Directly to Crops

Statistic	Enterovirus	Giardia	Cryptosporidium	E. coli O157
Minimum Median 0.9 Maximum Mean Standard deviation	$0 \\ 7.00 \times 10^{-7} \\ 6.66 \times 10^{-5} \\ 9.58 \times 10^{-1} \\ 3.68 \times 10^{-4} \\ 1.17 \times 10^{-2}$	$\begin{array}{c} 1.19 \times 10^{-10} \\ 8.54 \times 10^{-5} \\ 8.52 \times 10^{-3} \\ 1.00 \\ 1.21 \times 10^{-2} \\ 7.34 \times 10^{-2} \end{array}$	5.75×10^{-10} 2.04×10^{-4} 1.70×10^{-2} 1.00 1.82×10^{-2} 9.22×10^{-2}	$0\\8.45 \times 10^{-8}\\8.07 \times 10^{-6}\\1.08 \times 10^{-2}\\2.01 \times 10^{-5}\\2.38 \times 10^{-4}$

Note: Summary of annualized risks of infection assuming all exposures in the year are to crops irrigated with recycled water (1.3 mL/day).

annualized risks of infection, based on the representative microbial concentrations and daily exposure scenarios described previously, are at the 1 per 10,000 level or lower of infection. The CDPH considers a 1 in 10,000 (i.e., 1×10^{-4}) mean annual risk of infection to be an acceptable risk from exposure to treated wastewater effluent.

From a risk management perspective, it may be useful to consider the 75th, 90th, and 95th percentile risk estimates if the policy is to be more conservative in protecting against infection. In Hamilton et al. (2006), the risk assessment focus was placed on the 95th percentile. In the Tanaka et al. (1998) risk assessment, both the 90th and 95th percentiles were considered, and focus was placed on the 95th percentile based on the U.S. EPA's Surface Water Treatment Rule (SWTR) criterion that turbidity in finished water be below the maximum level at least 95% of the time. However, in estimating annualized risk, the authors define the term expectation of annual risks as an average value of the risks for many exposures. Further, it may be argued that this may be overly stringent; Regli et al. (1988) reported risks that are generally higher from swimming in natural waters, and Cabelli et al. (1979, 1982) suggested even 1 order of magnitude larger risks are still acceptable to voluntary swimmers. As another example, the existing Ambient Water Quality Criteria for bacteria in recreational waters are set to limit the rate of highly credible gastrointestinal illness in

Table 7. Scenario II: Secondary Disinfected, Not Directly Applied to Edible Portion of Crop

Statistic	Enterovirus	Giardia	Cryptosporidium	E. coli O157
Minimum	0	1.09×10^{-9}	3.87×10^{-9}	0
Median	2.69×10^{-7}	4.70×10^{-5}	5.78×10^{-5}	1.23×10^{-6}
0.9	5.52×10^{-6}	1.25×10^{-3}	1.32×10^{-3}	1.99×10^{-4}
Maximum	1.98×10^{-3}	5.17×10^{-1}	3.01×10^{-1}	1.00
Mean	4.18×10^{-6}	1.11×10^{-3}	9.95×10^{-4}	1.04×10^{-3}
Standard	3.18×10^{-5}	9.01×10^{-3}	6.59×10^{-3}	1.56×10^{-2}
deviation				

Note: Summary of annualized risks of infection assuming all exposures in the year are to crops irrigated with reclaimed water (0.1 mL/day).

Table 8. Scenario III: Secondary Undisinfected Effluent, Not Directly Applied to Edible Portion of Crop

Statistic	Enterovirus	Giardia	Cryptosporidium	E. coli O157
Minimum Median 0.9 Maximum Mean Standard deviation	3.10×10^{-10} 1.08×10^{-6} 1.37×10^{-5} 1.36×10^{-3} 7.58×10^{-6} 3.39×10^{-5}	$\begin{array}{c} 1.20 \times 10^{-9} \\ 6.49 \times 10^{-5} \\ 1.87 \times 10^{-3} \\ 7.36 \times 10^{-1} \\ 1.72 \times 10^{-3} \\ 1.36 \times 10^{-2} \end{array}$	9.67×10^{-9} 9.15×10^{-5} 1.80×10^{-3} 3.25×10^{-1} 1.22×10^{-3} 7.23×10^{-3}	1.60×10^{-10} 1.08×10^{-4} 2.08×10^{-3} 6.34×10^{-1} 1.38×10^{-3} 9.10×10^{-3}

Note: Summary of annualized risks of infection assuming all exposures in the year are to crops irrigated with reclaimed water (0.1 mL/day).

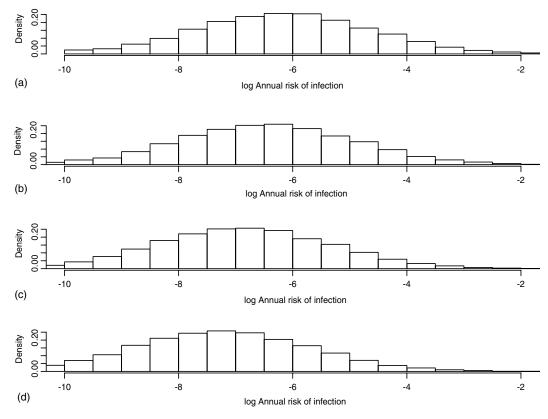


Fig. 3. Distribution of annualized risk for different exposure assumptions: (a) exposure every day; (b) exposure every other day; (c) exposure 70 days/year; (d) exposure 8% of the year

swimmers, based on a geometric mean of indicator organisms, to no more than 8 per 1,000 people per year (or 0.008 pppy) in freshwater and 19 per 1,000 in marine waters (or 0.019 pppy) (U.S. EPA 1986).

Sensitivity Analyses

Several sensitivity analyses were explored. Except where noted, all sensitivity analyses were performed for enterovirus with tertiary treatment and direct application to edible crops (see Scenario I).

The first analysis considers that not all exposures over the year are likely to be to crops irrigated with recycled water. As described in "California Water Reuse," projections suggest that recycled water may be applied to approximately 8% of crops rather than all crops. Adjusting exposure to 8% of the crops grown with recycled water over the year results in annualized risks for Scenario I of approximately 1 order of magnitude lower than the risks of assuming exposure to recycled water-irrigated crops every day.

A more comprehensive analysis of the numbers of days of exposure is presented in Fig. 3, which illustrates the shift in the distribution of modeled annualized risks for different exposure assumptions: exposure every day of the year, exposure every other day, exposure 70 days out of the year [consistent with assumptions made by Khan (2008)], and exposure on 8% of days in the year. Expected risk results are relatively insensitive to this exposure factor, varying by 1.5 orders of magnitude.

Second, a sensitivity analysis was performed on the number of days of environmental decay, and an alternative decay rate from Asano et al. (1992) of $k=0.69~{\rm day^{-1}}$ was considered. The annualized risk results for different assumptions are shown in Table 9. The risk results are highly sensitive to environmental decay

Table 9. Sensitivity Analysis for Enterovirus Annualized Risk Estimates of Environmental Decay Rates

k rate	Statistic	1 day	7 days	14 days
Asano et al. (1992)	Median	6.46×10^{-4}	1.03×10^{-5}	8.21×10^{-8}
Asano et al. (1992)	Mean	3.71×10^{-2}	2.51×10^{-3}	4.32×10^{-5}
Asano et al. (1992)	Standard deviation	1.38×10^{-1}	3.04×10^{-2}	1.40×10^{-3}
Petterson et al. (2001)	Median	4.35×10^{-4}	7.00×10^{-7}	4.65×10^{-10}
Petterson et al. (2001)	Mean	2.99×10^{-2}	3.68×10^{-4}	7.35×10^{-7}
Petterson et al. (2001)	Standard deviation	1.23×10^{-1}	1.17×10^{-2}	4.91×10^{-5}

Note: Log reduction over time.

assumptions, varying by 4 to 6 orders of magnitude, depending on the assumption.

Third, a sensitivity analysis was performed on treatment efficacy. In this analysis, a single point estimate of log removal was specified to generate annualized risk. The distributions of annualized risk for different log-removal efficacy (i.e., log removal varies from 1 to 8 logs) assumptions are shown in Fig. 4. Risks vary across a wide range because a wide range of treatment efficacies was considered. Generally, each additional log removal results in approximately 1 order of magnitude lower annual risk.

Finally, for Scenarios II and III, which consider applications of water reuse to non-edible portions of crops, an alternative exposure assumption that was 1 order of magnitude lower was considered (ingestion volume of 0.01~mL/day). This resulted in the annualized

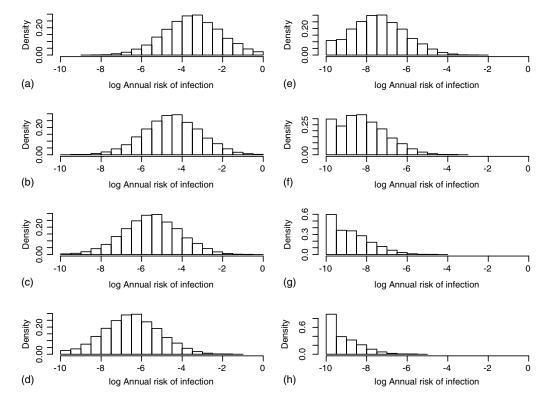


Fig. 4. Sensitivity analysis of treatment efficacy: (a) 1 log removal; (b) 2 log removal; (c) 3 log removal; (d) 4 log removal; (e) 5 log removal; (f) 6 log removal; (g) 7 log removal; (h) 8 log removal

risks that are approximately 1 order of magnitude lower than their higher exposure counterparts.

In summary, the analyses indicate approximately linear sensitivities to treatment efficacy (1 order of magnitude risk per 1-log removal), and especially large sensitivities with respect to environmental decay assumptions (4 to 6 orders of magnitude in risk). The risk results are relatively insensitive to days of exposure (1.5 orders of magnitude). Results for Scenarios II and III are somewhat insensitive to exposure volumes assumed (1 order of magnitude reduction of risk for 1 order of magnitude lower volume). Sensitivity of risk results to dose-response parameters, which are also subject to uncertainty and population variability, was not explored. Yet, it is expected that incorporation of dose-response variability and uncertainty would also broaden the distribution of risk.

Relationship between Panel Findings and Previous Risk Assessment Modeling Studies

Tanaka et al. (1998) evaluated four exposure scenarios, including one for food crop irrigation (using enteric virus data collected from unchlorinated secondary effluent grab samples from wastewater plants in southern California) with the goal of determining whether the 1989 U.S. EPA's SWTR for acceptable risk (less than 1 infection per 10,000 population per year) is met. Their approach is similar to that of the Panel's QMRA, which is based on assessing the distribution of concentrations before and after tertiary treatment, factoring in ingested dose based on exposure assumptions and using a dose-response relationship to estimate risk. They assume virus reductions according to the Pomona Virus Study (County Sanitation Districts of Los Angeles 1977), in which seeded poliovirus was recovered from tertiary treatment processes (County Sanitation Districts of Los Angeles 1977; Dryden et al. 1979). Their

assumptions for crop irrigation exposure are that consumers are exposed every day to 10 mL of recycled water through the ingestion of spray-irrigated food. Also, it is assumed that irrigation is stopped 2 weeks before harvest and shipment and that virus reduction occurs from sunlight exposure over this period, which follows an exponential decay e^{-kt} , where $k = 0.69 \text{ day}^{-1}$ and t = 14 days as assumed by Asano et al. (1992). Accordingly, over 14 days the proportion of remaining virus is 0.00006. Finally, a beta-Poisson rotavirus dose-response (Rose and Gerba 1991) was used.

Working backwards, Tanaka et al. (1998) found that between 0 and 2.1 log removal of enteric virus by tertiary treatment is necessary to reliably reach the SWTR 95% of the time. Also, they found that based on the Pomona Virus Study log-removal efficiencies (which range from 3.9 to 5.2 logs), tertiary treatment should be 100% reliable at meeting the SWTR at the plants where virus was measured. In addition, their expected annualized risks ranged from approximately:

- 10⁻¹⁰ to 10⁻⁸ for secondary, filtered, and chlorinated treatment (5.2-log removal);
- 10⁻⁷ to 10⁻⁹ for chlorination of secondary effluent (3.9-log removal); and
- 10⁻⁵ to 10⁻³ for unchlorinated secondary effluent (0 log removal).

Using their assumptions, the Panel's QMRA model was able to reproduce the Tanaka et al. findings to the same order of magnitude.

The study by Hamilton et al. (2006) provides another comparison. This study reassessed Tanaka et al. (1998) wastewater plant data from southern California, but used an updated exposure relationship (the same as the approach in this paper) and allowed for three different amounts of environmental decay (1, 7, and 14 days). Their annualized infection risk for lettuce consumption with a 7-day decay period for the application of nondisinfected secondary recycled water ranged from 10^{-4} to 10^{-3} . Their risk estimates, as

expected, are considerably higher than those developed as part of the previous analysis for Scenario III of lettuce consumption based on fully disinfected tertiary treatment.

Discussion

In interpreting the QMRA findings, one of the most important issues that should be addressed is defining acceptable or tolerable risk as it relates to water recycling for nonpotable uses. Evaluating the adequacy of a particular treatment train requires a benchmark level (or set of criteria) that can be used for comparison. Selecting a benchmark level of risk is a complicated process that involves the evaluation of technical, political, and social factors, which is outside of the Panel's charge. However, to provide input and guidance to CDPH on this subject, the Panel utilized a weight-of-evidence approach that looked at four key factors:

- · Current regulatory examples of acceptable and/or tolerable risk;
- CDPH historical background information and assumptions regarding public health risk associated with developing recycled water standards;
- · Past and current QMRAs for recycled water; and
- Comparison of estimated public health risk to diarrheal disease incidence rates in the United States.

There are a number of examples of how acceptable risk has been defined that are described as follows:

- For the SWTR (which was developed as one component of the Safe Drinking Water Act), a risk of 1 infection per 10,000 people per year (or 0.0001 pppy) was taken as a reasonable and acceptable health goal (Macler and Regli 1993). As drinking water regulations evolved, so did the process that is used to evaluate the adequacy of treatment. One of the more recent drinking water regulations, the Long Term 2 Enhanced Surface Water Treatment Rule (LT2 Rule), requires public water systems to augment their water treatment processes if the mean source water Cryptosporidium levels correspond to an estimated annual infection level of 2 per 1,000 persons or greater (U.S. EPA 2006). The process that was used to arrive at the levels described in the Final LT2 Rule involved review by a scientific advisory committee, public comment, and numerous technical considerations, including monitoring feasibility.
- As another example, the existing Ambient Water Quality Criteria for bacteria in recreational waters are set to limit the rate of highly credible gastrointestinal illness in swimmers to no more than 8 per 1,000 (or 0.008 pppy) in freshwater and 19 per 1,000 in marine waters (or 0.019 pppy), based on geometric mean values for indicator organisms (U.S. EPA 1986).
- WHO (2004) defined the tolerable risk of disease for fully treated drinking water to be 1 per 1,000 (or 0.1% of disease in the community per year). Some public health experts have indicated that a more acceptable level of risk should be based on infection and be on the order of 1 per 100 (or 1% of the community infected per year) (Mara et al. 2007).

A brief review of the historical CDPH record (California Department of Health Services 1991, 1987) for the development of the CDPH water reuse regulations and the CDPH guidance on wastewater disinfection indicates the following:

• The acceptable incidence of symptoms for diarrhea, fever, rash, infectious hepatitis, and vomiting for persons exposed to recycled water was estimated to be 4 per 100,000 (this could be as low as 1 per 100,000, depending on the symptom or disease), and the assumed probability of infection associated with the previous symptoms is on the order of 1 per 1,000 [based on a ratio of disease to infection of 1 to 100 (Pipes 1978)].

• The assumptions used to estimate an acceptable risk of infection for swimming in receiving waters where secondary treated disinfected wastewater is discharged (total coliform <23 MPN/100 mL) and 100 mL of water is consumed was calculated by CDPH staff to be on the order of 2 per 1,000 for Giardia lamblia and 8 per 100,000 for enteroviruses (Polio I). The CDPH report notes that the estimates reduced the 1986 U.S. EPA acceptable risk of illness for recreation by roughly 50%.</p>

Currently, there are no federal or state laws and/or regulatory standards defining acceptable risk for nonpotable water recycling. While numerical standards are useful, they can never be applicable and/or protective for all exposures, all pathogens, and all individuals. Further, from a public health perspective, they may or may not be necessary depending on how regulations are developed, implemented, and enforced. While this is the case for the California Water Recycling Criteria, CDPH appropriately developed treatment-based standards that include the need for multiple barriers, a high level of plant reliability, and process redundancy.

CDPH implementation of the Water Recycling Criteria is based on a goal that the treatment-based standards provide sufficient overall plant reliability to achieve the U.S. EPA SWTR (i.e., potable drinking water) acceptable risk goal of one infection per 10,000 people per year for enteric viruses (applied as a mean). Achieving the SWTR acceptable risk goal was evaluated from a plant reliability perspective at four California water recycling operations (i.e., Orange County Sanitation District separately for activated sludge and trickling filter processes, Pomona, and the Monterey Regional Water Pollution Control Agency) for a number of exposure routes, including food crop irrigation (i.e., based on the assumption that crops are consumed every day, 10 mL of exposure volume per day, no irrigation for 2 weeks before harvest, and sunlight inactivation) for enteric viruses. Tanaka et al. (1998) concluded that the estimated annual risks of infection for full treatment (i.e., secondary plus filtration per the recycling criteria) or contact filtration (i.e., direct filtration) and high chlorine dose (i.e., 5.2-log removal of seeded polio virus) and for secondary treatment and high chlorine dose (i.e., 3.9-log removal) are less than 1 per 10,000, even at a 95% confidence level (CL). In addition, Olivieri et al. (2007) recently conducted a microbial risk assessment for several nonpotable reuses (i.e., full body contact-unrestricted recreation, landscape irrigation—restricted and unrestricted, and food crop irrigation-edible and non-edible) and concluded that the estimated daily risk of infection for exposure through food crop irrigation was approximately:

- A median of 3.1 to 3.9 per 100,000 (disinfected secondary) to 1 per 100,000 to 4.5 per 1,000,000 (disinfected tertiary) for parasites (i.e., Giardia and Cryptosporidium spp.); and
- A median of 1.7 per 100,000 (disinfected secondary) to 3.9 per 1,000,000 (disinfected tertiary) for enteric viruses.

Although Tanaka et al. (1998) and Olivieri et al. (2007) employed slightly different assumptions for exposure, dose-response, field decay period, and treatment effectiveness, a comparison of the overall results for the risk of infection from enteric viruses for water recycling on edible food crops is within an order of magnitude.

Summary and Conclusion

The results of the QMRA conducted as part of this Panel's investigation indicate that annualized median risks of infection for full tertiary treatment range from 10^{-8} to 10^{-4} (for the selected pathogens), and accounting for the likelihood that only 8% of crops will be irrigated with recycled water, the annualized median risks are an order of magnitude lower, 10^{-9} to 10^{-5} . Furthermore, the estimated

median risks are for infection rather than disease (not all infections result in clinical disease).

To bring this paper into overall perspective, the estimated diarrheal disease incidence for all ages in developed countries is on the order of 0.2 per person per year (pppy) (Mathers et al. 2002) to 0.72 per person per year (Imhoff et al. 2004). A reanalysis of the FoodNet population survey data in the United States for the period 2000-2003 resulted in an adjusted rate of 0.65 pppy (Roy et al. 2006). Comparison of the 0.2 pppy disease incidence (assuming that the ratio of infection to disease is 1, which is highly conservative and unlikely) against the tolerable and/or acceptable levels currently used for drinking water and surface water regulations indicates that those levels are several (at least 2) orders of magnitude lower than the diarrheal disease incidence in developed countries and, most likely, would not measurably raise the incidence level. This comparison does not assume that the Panel considers the diarrheal disease incidence rate acceptable. However, the previous weight of evidence allowed the Panel to address two key questions:

- Should CDPH develop an acceptable or tolerable risk metric for water-recycling criteria reuse applications? Based on the Panel's review and analysis, the Panel did not believe at the time that developing an acceptable or tolerable risk metric was warranted.
- 2. Is there any evidence that the current treatment-based Water Recycling Criteria increase the risk to public health through irrigation of food crops with recycled water? The Panel's review of the available weight of evidence, including past (Tanaka et al. 1998; Olivieri et al. 2007) and current QMRA results, confirms that current agricultural practices consistent with the Water Recycling Criteria do not increase public health risk and that modifying the standards to make them more restrictive will not improve public health.

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