



Examining the Criteria for Direct Potable Reuse

WateReuse Research Foundation

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The mission of the WateReuse Research Foundation is to conduct and promote applied research on the reclamation, recycling, reuse, and desalination of water. The Foundation's research advances the science of water reuse and supports communities across the United States and abroad in their efforts to create new sources of high-quality water through reclamation, recycling, reuse, and desalination while protecting public health and the environment.

The Foundation sponsors research on all aspects of water reuse, including emerging chemical contaminants, microbiological agents, treatment technologies, salinity management and desalination, public perception and acceptance, economics, and marketing. The Foundation's research informs the public of the safety of reclaimed water and provides water professionals with the tools and knowledge to meet their commitment of increasing reliability and quality.

The Foundation's funding partners include the Bureau of Reclamation, the California State Water Resources Control Board, the California Energy Commission, and the California Department of Water Resources. Funding is also provided by the Foundation's subscribers, water and wastewater agencies, and other interested organizations.

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Final Report

Examining the Criteria for Direct Potable Reuse

Recommendations of an NWRI Independent Advisory Panel

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National Water Research

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- David Smith, Ph.D., WateReuse California
- David White, U.S. Department of Interior, Bureau of Reclamation

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- Robert Hultquist, P.E., California Department of Public Health (retired annuitant)
- Ian B. Law, IBL Solutions (Australia)
- David W. Sloan, P.E., BCEE, Freese and Nichols
- George Tchobanoglous, Ph.D., P.E., University of California, Davis (Emeritus)

In addition, the workshop was instrumental in bringing together a broad range of researchers, academics, water and wastewater agency representatives, regulators, and other experts to review and discuss questions and issues regarding the Panel's efforts. The Panel would like to thank the workshop participants, who are listed in Appendix C.

Finally, the Panel would like to express gratitude to WRRF, Trussell Technologies, Inc., and NWRI for the opportunity to serve on this Panel. The Panel is grateful for the many questions and suggestions received from these collaborative partners.

Members of the Panel include:

- *Chair*: James Crook, Ph.D., P.E., Environmental Engineering Consultant (Boston, MA)
- Richard Bull, Ph.D., MoBull Consulting (Richland, WA)
- Harvey F. Collins, Ph.D. P.E., Environmental Engineering Consultant (Sacramento, CA)
- Joseph A. Cotruvo, Ph.D., Joseph Cotruvo and Associates (Washington, D.C.)
- Walter Jakubowski, WaltJay Consulting (Spokane, WA)

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ACRONYMS

ADD	Acceptable daily dose
ADI	Acceptable daily intake
AOP	Advanced oxidation process
ATSDR	Agency for Toxic Substances and Disease Registry
CA OEHHA	California Office of Health Hazard Assessment
CCL	Contaminant Candidate List
CDPH	California Department of Public Health
DBP	Disinfection byproduct
DEET	N,N-Diethyl-meta-toluamide
DNA	Deoxyribonucleic acid
DPR	Direct potable reuse
DWEL	Drinking water equivalent level
HA	Health advisory
HAAs	Haloacetic acids
HRL	Health Reference Levels
IPR	Indirect potable reuse
LOAEL	Lowest Observed Adverse Effect Level
MCL	Maximum contaminant level
MCLG	Maximum contaminant level goal
MF	Microfiltration
MOE	Margin of exposure
MRDD	Maximum recommended daily dose
MRL	Minimum risk level
MRTD	Maximum recommended therapeutic dose
MS2	Male specific
NDMA	N-Nitrosodimethylamine
NF	Nanofiltration
NRC	National Research Council
NWRI	National Water Research Institute
OPP	Office of Pesticides Programs
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctane sulfonate
PHG	Public health goal
RBAL	Risk-based action limit
RfD	Reference dose
RNA	Ribonucleic acid
RO	Reverse osmosis
RSC	Relative source contribution
SAT	Soil aquifer treatment
SWTR	Surface Water Treatment Rule
TCEP	Tris[2-chloroethyl]phosphate
THM	Trihalomethane
TOC	Total organic carbon
TTC	Threshold of toxicological concern

UCMR2	Unregulated Contaminants Monitoring Rule
U.S. EPA	United States Environmental Protection Agency
U.S. FDA	United States Food and Drug Administration
UF	Ultrafiltration
UV	Ultraviolet radiation
VOC	Volatile organic compound
WHO	World Health Organization
WRRF	WaterReuse Research Foundation

ABBREVIATIONS FOR UNITS OF MEASURE

kg	Kilogram
L	Liter
mg	Milligram
mg/kg	Milligrams per kilogram
mg/L	Milligrams per liter
mL	Milliliter
ng/L	Nanograms per liter
nm	Nanometer
NTU	Nephelometric turbidity unit
μg/L	Micrograms per liter
μm	Micrometer

1. INTRODUCTION

Trussell Technologies, Inc., an environmental engineering consulting firm based in Pasadena, California, was awarded a WateReuse Research Foundation (WRRF) grant in 2011 to investigate the Equivalency of Advanced Treatment Trains for Potable Reuse (WRRF 11-02). Potable reuse involves the use of municipal wastewater that has been treated to meet specific water quality criteria with the intent of being used for potable purposes. Due to increased demand and the need for reliable supplies, indirect potable reuse (IPR) has become more prevalent within the United States and abroad. IPR may be defined as the augmentation of a drinking water source (surface or groundwater) with reclaimed water followed by an environmental buffer that precedes normal drinking water treatment. An environmental buffer, which provides retention time and may also provide additional treatment, can be groundwater or a surface water body. For surface water, an environmental buffer is a water body (e.g., reservoir or river) into which product water from a water reuse facility (i.e., a conventional or advanced wastewater treatment plant that produces reclaimed water [also called recycled water]) is placed prior to being withdrawn for drinking water treatment. For groundwater recharge, an aquifer acts as the environmental buffer into which product water from a water reuse facility is placed prior to extraction at a potable water extraction well. However, interest is now expanding to direct potable reuse (DPR), which does not include an environmental buffer and is defined as the introduction of product from a water reuse facility into a raw water supply immediately upstream of, or directly into, a drinking water treatment plant or directly into a potable water distribution system.

To facilitate the transition to DPR, the Trussell Technologies, Inc. project will assess the equivalency of advanced treatment trains and determine what modifications – if any – are necessary to satisfy the public health criteria for DPR. As part of this effort, Trussell Technologies, Inc. retained the National Water Research Institute (NWRI) of Fountain Valley, California, in 2012 to coordinate an Independent Advisory Panel (Panel) to lead a 2-day workshop to develop a set of criteria that are protective of public health to evaluate treatment technologies for DPR.

Members of the Panel include:

- *Chair*: James Crook, Ph.D., P.E., Environmental Engineering Consultant (Boston, MA)
- Richard Bull, Ph.D., MoBull Consulting (Richland, WA)
- Harvey F. Collins, Ph.D. P.E., Environmental Engineering consultant (Sacramento, CA)
- Joseph A. Cotruvo, Ph.D., Joseph Cotruvo and Associates (Washington, D.C.)
- Walter Jakubowski, WaltJay Consulting (Spokane, WA)

A short biography of each Panel member is included in Appendix A.

Prior to the workshop, each Panel member received the draft WRRF report, *Equivalency of Advanced Treatment Trains for Potable Reuse*, prepared by R. Rhodes Trussell, Andrew Salveson, Shane A. Snyder, R. Shane Trussell, and Daniel Gerrity.¹ The report included sections on the following:

¹ This report will be published by WRRF under WRRF Project 11-02.

- State of the Science
- Public Health Criteria for Potable Reuse
- Model Development
- Treatment Train Validation

In addition, the Panel received background information prepared by Trussell Technologies, Inc. on the following topics:

- Criteria that Are Protective of Public Health to Evaluate Treatment Technologies for DPR: Strawman Overview
- The Concept of Risk: A Strategy for Contaminant Goals in Potable Reuse
- Criteria that Are Protective of Public Health to Evaluate Treatment Technologies for DPR: Strawman Pathogens
- Free of Wastewater Properties Evident to the Informed Consumer
- Trace Chemicals to Monitor in Potable Reuse: A Continuously Evolving List

The Panel met via conference call on August 20, 2012, to discuss these items and to clarify workshop objectives in advance of the workshop. There were also subsequent conference calls and numerous communications via electronic mail to clarify issues.

The workshop itself was held on August 29-30, 2012, at the Central Power Yard Conference Room at the Los Angeles Department of Water and Power in Los Angeles, California. The workshop objectives included:

- Review the draft report prepared by the project team and information presented at the workshop.
- Comment on the proposed criteria for pathogens, including: pathogen selection, removal goals, removal criteria, level of acceptable risk, need for multiple barriers, and the use of indicators and surrogates.
- Comment on the proposed criteria for chemical contaminants, including: current regulated contaminants, unregulated compounds, acceptable risk, and the use of indicators and surrogates.
- Comment on the need for criteria for related topics, such as monitoring, operations and maintenance, treatment reliability and redundancy, engineered buffer and time to react, and public perception.
- Draft an outline for the Panel report.

As part of the agenda, presentations on the following topics were made by members of the project team and/or leading experts on DPR:

- Design and Operational Criteria for Big Spring, Texas: Implementing Raw Water Blending by David W. Sloan, P.E., BCEE, Freese and Nichols
- *Examples of Overseas Design and Operating Criteria* by Ian B. Law, IBL Solutions (Australia)
- *Technology Review for Potable Reuse* by R. Shane Trussell, Ph.D., P.E., BCEE, Trussell Technologies, Inc.

- National Research Council Report on "Water Reuse" by Shane A. Snyder, Ph.D., University of Arizona
- *Direct Potable Reuse: The Next Frontier* by George Tchobanoglous, Ph.D., P.E., University of California, Davis (Emeritus)
- Strawman by R. Rhodes Trussell, Ph.D., P.E., Trussell Technologies, Inc.
- *Direct Potable Reuse: A Drinking Water Regulator's Perspective* by Robert Hultquist, P.E., California Department of Public Health (retired annuitant)

These presentations are available electronically at the NWRI website at <u>http://www.nwri-usa.org/criteriapanel.htm</u>.

The workshop agenda is included in Appendix B. All Panel members attended the workshop. In addition, over 80 representatives from various water and wastewater agencies, research organizations, universities, consulting firms, and local and state governments, participated in the workshop. A complete list of workshop attendees is included in Appendix C.

2. FINDINGS AND RECOMMENDATIONS

2.1 General Comments

The Panel considers the microbial and chemical constituent criteria presented in this report to evaluate treatment technologies for DPR to be protective of public health. The use of the constituent criteria are not suggested regulatory water quality criteria for reclaimed water used for DPR and are not intended to preempt the decision process for regulators, who must take numerous factors into consideration when establishing enforceable regulations. The Panel recognizes that some criteria are meant more as measures of performance of the treatment trains. The actual parameters that might be applied to a given DPR project need to be more specifically related to a characterization of the particular wastewater being proposed as a source water for DPR.

The Panel recognizes that, in addition to the microbial and chemical constituent criteria presented in this report for evaluating treatment technologies, other criteria are needed to ensure public health protection for DPR. Among other topics, such criteria would need to address: treatment process reliability and redundancy; source control; monitoring methodology and frequency; operations and maintenance; reporting; alternate means of disposal (or retreatment) of inadequately-treated water; and time to react to events of contaminant breakthrough (retention time). Consideration of these and other related topics (e.g., costs, feasibility, and public perception) are not within the scope of the Panel's charge and, thus, are not addressed in this report.

2.2 Criteria for Microbial Organisms to Evaluate Treatment Technologies for DPR

2.2.1 Background

The history of the water industry in the United States and elsewhere has demonstrated the potential for significant morbidity and mortality by ingestion of pathogens in inadequately treated or distributed drinking water supplies. The development of processes such as filtration and disinfection to remove or inactivate waterborne pathogens has resulted in major advances in public health.

While selecting a protected source for a public drinking water supply is still sound advice, it is becoming increasingly difficult to find "natural" source waters that are not impacted to some extent by wastewater discharges. Sewage and wastewater discharges to receiving waters are a primary source of the enteric pathogens (bacteria, viruses, and protozoa) that have been associated with acute diseases from drinking water.

To ensure that pathogenic microorganisms are not transmitted to any significant extent by drinking water produced through potable reuse projects, adequate criteria need to be established for removing or inactivating microorganisms by the treatment processes. Establishing these criteria requires considering a number of factors including: their occurrence; likely health effects (including the infective dose of the pathogens); efficacy of treatment processes; quantitative

microbial risk assessment; and appropriate safety factors to address variations in treatment processes (type and reliability), epidemic conditions, and uncertainty in risk assessment.

The project team has addressed all of these items in their draft report entitled *Equivalency of Advanced Treatment Trains for Potable Reuse*. Panel members considered this document in their review, as well as the following other sources: the recent National Research Council (NRC, 2012) report on expanding water supplies through the reuse of municipal wastewater; criteria proposed by federal, state, and municipal authorities; presentations by national and international experts at a workshop; additional expert advice; and their own experience in arriving at their recommendations.

2.2.2 Pathogen Removal Criteria

The operating benchmark criteria being proposed by this Panel for purposes of this study are total log_{10} removals of microorganism groups from raw sewage through to the final product water (Table 1).

Microbial Group	Criterion (Log ₁₀ Removal)	Possible Surrogates	Source Used to Develop Criteria
Enteric Virus	12	MS2 bacteriophage	SWTR (U.S. EPA, 1989a); CDPH (2011); NRC (2012); NRMMC–EPHC– NHMRC (2008)
<i>Cryptosporidium</i> spp. ^a	10	Latex microspheres, AC Fine Dust, inactivated <i>Cryptosporidium</i> oocysts, aerobic spores	Interim ESWTR (U.S. EPA, 1998); LT2 ESWTR (U.S. EPA, 2006); CDPH (2011); NRC (2012); NRMMC–EPHC– NHMRC (2008)
Total Coliform Bacteria ^b	9	NA ^c	Total Coliform Rule (U.S. EPA, 1989b); NRC (2012) risk assessment for salmonella

 Table 1. Microbial Removal Criteria for Evaluation of Treatment Trains

 and Protection of Public Health

^aAddresses *Giardia* and other protozoa as well.

^bAddresses enteric pathogenic bacteria, such as *Salmonella* spp.

 $^{\circ}$ NA = Not Applicable.

The Panel concluded that the suggested upperbound removal criteria for enteric virus, *Cryptosporidium*, and total coliform bacteria would, if met by the combined wastewater, reclaimed water, and drinking water treatment processes, ensure that reclaimed water would be free of pathogenic microorganisms with a large margin of safety (probably greater than being achieved for many conventional water supplies) and could be safely used for potable purposes.

For example, should product water from a water reuse facility be discharged directly into a potable water distribution system, the removal criteria shown in Table 1, if met by the water

reuse facility, would be protective of public health. On the other hand, should the product water be discharged to the intake to a drinking water treatment plant, public health would be protected provided the water reuse facility and the drinking water treatment plant combined met the criteria shown in Table 1. Pursuant to the U.S. Environmental Protection Agency's (U.S. EPA) Surface Water Treatment Rule (SWTR), drinking water treatment plants treating surface water, or water under the influence of surface water, must meet a 4 log₁₀ removal of virus and a 2 to 3 or more log₁₀ removal of *Cryptosporidium*. The SWTR gives 3 logs of *Cryptosporidium* removal credit for conventional treatment and several other related technologies, plus additional credits for other technologies like ultraviolet radiation (UV) and ozonation. Therefore, depending upon the subsequent drinking water treatment, the water reuse facility would need to meet up to 8 log₁₀ removal of virus and up to 7 log₁₀ removal of *Cryptosporidium*, which combined with the removals provided by the drinking water treatment plant would meet the criteria in Table 1.

The SWTR does not require a specific removal of total coliform bacteria, but it does specify a maximum contaminant level goal (MCLG) of zero and requires a maximum contaminant level (MCL) of 0/100 milliliters (mL) and compliance monitoring. These requirements, therefore, do not translate directly into a log₁₀ removal for total coliform. Furthermore, the Panel is aware that the U.S. EPA proposes to eliminate the MCLG and MCL for total coliform and maintain an MCLG and MCL of zero for *Escherichia coli* (*E. coli*), which also do not translate directly into a log₁₀ removal. Therefore, the Panel concluded that as long as the water reuse facility and the drinking water treatment plant jointly meet the 9 log₁₀ removal of total coliform specified in Table 1, public health will be protected.

The stated goal of the \log_{10} removal criteria presented in Table 1 is to achieve finished drinking water that would not exceed 10^{-4} annual risk of infection if the water is consumed as normal drinking water. These suggested target criteria would likely achieve calculated risks in treated water that would be lower than the 10^{-4} target upper bound risk and, thus, would be protective of public health even during disease outbreaks. The suggested operating benchmark criteria for these three groups of microorganisms are discussed further in the section below.

2.2.3 Rationale for Selection

Enteric Viruses. There are numerous types of enteric viruses potentially present in sanitary wastewater when infected persons are shedding the microorganisms. Although there is evidence that some rotaviruses may be zoonotic, essentially only enteric viruses of human origin are infective to humans. Viruses are readily inactivated by free chlorine and other primary disinfectants, such as ozone. UV is also effective, but deoxyribonucleic acid (DNA) viruses like adenovirus are more resistant to UV than are ribonucleic acid (RNA) viruses like rotaviruses and echoviruses, so higher doses are required for them if UV is used in the absence of prior chemical disinfection. Because viruses are equivalent to very high molecular weight organic molecules, they are readily removed by membrane filtration, especially ultrafiltration (UF), nanofiltration (NF), and reverse osmosis (RO). Pathogenic viruses are difficult to monitor for individually, but male specific (MS2) bacteriophage is similar in size, shape, and RNA content to enteric viruses and is a well-accepted surrogate that can be readily monitored as a treatment performance indicator. MS2 bacteriophages are viruses that infect *E. coli*; they are present in sanitary

wastewaters in much greater numbers than are human pathogens, so their reduction is a conservative gauge for the removal of other viruses.

As shown in Table 1, the Panel determined that a log_{10} removal of 12 for enteric virus would provide a *de minimus* annual risk of infection (less than 10^{-4} , assuming a raw sewage starting point concentration of 10^5 per liter [L]) from using reclaimed water for potable purposes. This level of computed risk as a goal for treated drinking water has been accepted by the U.S. EPA and state drinking water administrators for many years. Furthermore, the Panel concluded that this criterion contains a safety factor of several orders of magnitude and, therefore, would be protective of public health even during an outbreak when high concentrations of virus are being shed to the sewer. Therefore, this level of protection would be usable as a very conservative operating criterion for the purposes of this study. The Panel based this conclusion on the fact that several conservative assumptions were employed (i.e., use of maximum versus average concentrations in raw sewage; use of infectivity data from the most infectious virus, which might not be the most commonly occurring; and assuming that every infection will cause an illness).

Cryptosporidium spp. Pathogenic intestinal protozoa are present in municipal wastewater when infected persons are shedding the microorganisms; intestinal protozoa from animal wastes may also be deposited on watersheds and subsequently enter storm and municipal wastewater via runoff. Many Cryptosporidium and Giardia species are not infective to humans. Due to their small size and resistance to free or combined chlorine, Cryptosporidium oocysts are among the most difficult microorganisms to inactivate or remove from water, although they are readily removed by microfiltration (MF), UF, NF, and RO. Giardia cysts, and especially *Cryptosporidium* oocysts, are more difficult to remove by chlorine disinfection than are bacteria. However, ozone, chlorine dioxide, and UV are more effective disinfectants for both Giardia and *Cryptosporidium*. *Cryptosporidium* oocysts are small protozoans (~4 to 6 micrometers [µm]) and are predominantly removed by size exclusion filtration with good granular media or membrane filtration. MF, UF, NF, and RO are effective in removing *Cryptosporidium* oocysts and other protozoa that are larger than bacteria and viruses. Achieving very low turbidity levels (<0.3 nephelometric turbidity unit [NTU]) is an indicator of good removal of Cryptosporidium and larger organisms (e.g., Giardia, which are 7 to 14 µm in size). UV application to low turbidity water will effectively inactivate both Cryptosporidium and Giardia that might remain after incomplete filtration and chemical disinfection.

The Panel determined that a log_{10} removal of 10 for *Cryptosporidium oocysts* would provide a *de minimus* annual risk of infection from using reclaimed water for potable purposes. The Panel concluded that the removal of *Cryptosporidium* oocysts to this level will also ensure the same or greater removal of *Giardia cysts*, since they are larger and more easily disinfected. A U.S. EPA study showed 3.4 log_{10} removal of *Giardia* cysts by conventional filtration versus 2.98 log_{10} removal of *Cryptosporidium* oocysts (U.S. EPA, 1997). Similar results were obtained for direct filtration (3.26 log_{10} removal for cysts versus 2.25 log_{10} removal for oocysts). There was considerable discussion among Panel members about whether or not the 10 log_{10} removal criterion for *Cryptosporidium* was overly conservative. Based on the information available to the Panel, it appears that this criterion is two to three orders of magnitude higher than required to meet the upperbound annual risk of 10⁻⁴. Considering the current state of knowledge and uncertainty about the occurrence, species, infectivity, and infective dose of *Cryptosporidium*, the Panel concluded that the $10 \log_{10}$ removal criterion for *Cryptosporidium* incorporates safety factors that would ensure the protection of public health even during outbreaks in a community. As new information becomes available, this criterion may be revised as appropriate.

Enteric Pathogenic Bacteria. Enteric pathogenic bacteria such as *Salmonella* spp. are present in sanitary wastewater when infected persons are shedding them. Bacteria are readily disinfected by primary disinfectants such as free chlorine, ozone, chlorine dioxide, UV, and to a lesser degree (i.e., more slowly) by chloramines. Coliform bacteria and *E. coli* are present in sanitary wastewater at concentrations much greater than enteric pathogens. They are easily monitored and accepted among the several bacterial surrogates for measuring the effectiveness of processes for the removal of bacteria and viruses. They are not suitable surrogates for the removal of protozoa. Bacteria and viruses are also effectively removed by conventional water treatment technologies that combine filtration and disinfection, as well as by membranes that include UF, NF, and RO. MF is also reasonably effective as biofouling improves its efficacy.

Total coliform bacteria can be present in water from numerous sources in addition to human or animal feces; *E. coli* are commonly more specifically associated with fecal contamination. Because bacterial pathogens are present in wastewater at much lower concentrations than indicator organisms, such as total coliforms or *E. coli*, criteria that utilize those indicator organisms (which can easily be measured with high sensitivity) will be highly protective of consumers from risk of bacterial infection. In contrast to the infective doses for viruses, the infective doses of many pathogenic bacteria are larger. Therefore, the removal of total coliform or *E. coli* bacteria to nondetectable levels (usually per 100 mL) provides a very high degree of assurance that infective doses of a bacterial pathogen would not be present in the treated water.

The Panel selected total coliform bacteria for the operating criterion for the study since they are present in sanitary wastewater at concentrations much greater than enteric pathogens and *E. coli*, and are easily monitored and accepted among the several bacterial surrogates for measuring the effectiveness of disinfection. The Panel concluded that a log_{10} removal of 9 for total coliform bacteria in the combined wastewater and drinking water treatment processes would provide a *de minimis* annual risk of infection from *Salmonella* spp. and other enteric bacterial pathogens, which assumes that the coliforms and pathogens are inactivated or removed with similar effectiveness by the treatment processes. The upper bound annual risk of 10⁻⁴ for *Salmonella* spp. infection was calculated using a Beta-Poisson dose-response model derived by using actual outbreak data (WHO-FAO, 2002). Since total coliforms are a conservative surrogate for pathogenic bacteria, it is probable that the actual risks being achieved are lower than 10⁻⁴.

2.3 Criteria for Chemical Contaminants to Evaluate Treatment Technologies for DPR

2.3.1 Background

Chemical criteria for DPR can be selected for several different reasons. The treatment train must produce water that meets all drinking water standards established to protect human health. In addition, there are a variety of chemicals of health concern whose occurrence is too infrequent in conventional drinking water sources to justify the establishment of national standards. The U.S.

EPA establishes health advisories (HAs) (U.S. EPA, 2012) to address many of these latter chemicals.

There is a distinct possibility that some chemicals with the potential of producing adverse health effects may occur in the wastewater being treated and possibly in the reclaimed water at concentrations that would be of health concern for which MCLs and HAs have not been derived. If such compounds are identified, it is important to establish criteria that would be equally protective of public health as chemicals for which drinking water standards have been established.

Finally, municipal wastewater will contain a wide variety of chemicals that occur at concentrations much below those that would result in adverse health effects. However, tracing the fate of selected chemicals in this group through the treatment train can provide insights into the performance of unit processes, as well as the entire treatment train. It may be important to develop criteria for at least some of those chemicals to assure the public that they are not of health concern. It should be made clear that these are not regulated levels.

2.3.2 Evaluation of Other Sources that Identify Doses that Present *De Minimis* Risk

Frequently, other official or non-official groups have suggested levels for specific chemicals that they feel are protective of health. However, some address very different risk/benefit considerations (e.g., maximum recommended therapeutic doses [MRTD]) than drinking water guidelines. In other cases, the methodologies used by different organizations to determine safe exposures from drinking water or food arrive at significantly different levels of exposure than those of the U.S. EPA, and this can be confusing. To the extent that a particular guideline has been established by the World Health Organization (WHO), U.S. EPA, or California Office of Health Hazard Assessment (CA OEHHA), the methodologies used are well defined and generally focus on the entire population. WHO and the U.S. EPA differ from one another on some basic assumptions (dose per body weight vs. dose per unit surface area for carcinogens, respectively), and in the reference person (60 kilogram [kg] body weight vs. 70 kg, respectively), resulting in different WHO risk estimates than U.S. EPA risk based on the same basic data set. The differences in the estimates of risk between the two institutions can be as large as an order of magnitude. Both approaches are protective of health. However, utilization of a U.S. EPA risk assessment carries less risk of being non-compliant with an MCL developed in the future in the United States. This jeopardy would not result if the WHO risk assessments were utilized in countries outside of the United States that rely on the WHO drinking water guidelines.

California has also established public health goals (PHGs) via CA OEHHA for numerous chemicals and notification levels via the California Department of Public Health (CDPH) that can be part of the assessment. For genotoxic carcinogens, PHGs are generally at 10⁻⁶ lifetime risk. Notification levels and MCLs take into account practical factors in the enforcement of rules, such as practical quantitation limits or considerations of costs and benefits (e.g., disinfection byproducts [DBPs] are allowed at higher levels because disinfection is considered necessary to protect public health). Consequently, these guidelines may be set at concentrations greater than 10⁻⁶ added lifetime risk. The California risk assessments are more likely to conform to current risk assessment assumptions than older U.S. EPA guidelines (e.g., volatile *N*-

nitrosamine PHGs are higher than those of U.S. EPA because they have adopted updated methods for scaling dose per unit body surface area among species that conform to U.S. EPA guidelines, but which have not been updated by the Agency. These differences should undoubtedly be rectified when the U.S. EPA updates their risk assessments for these compounds).

Other federal agencies (e.g., United States Food and Drug Administration [U.S. FDA]) or even other regulatory programs within the U.S. EPA (e.g., the Office of Pesticides Programs [OPP]) establish guidelines based on the same data that the U.S. EPA Office of Drinking Water utilizes, but usually focus on a reference dose (RfD) or similar construct so the actual value would need to be converted to a drinking water equivalent level (DWEL). The acceptable daily intake (ADI) or the margin of exposure (MOE) used by OPP, the minimum risk level (MRL) used by the Agency for Toxic Substances and Disease Registry (ATSDR), and the acceptable daily dose (ADD) used by the CA OEHHA are similar constructs. These may not consider relative source contribution (RSC) that is usually routinely applied by the Office of Drinking Water when establishing MCLs or HAs. As a general rule, these numbers can be brought into line with a DWEL by distributing the ADI into 2 L of water. The RSC values for drinking water are usually in the 20- to 80-percent range, with 20 percent being the most common default value for noncarcinogens, absent adequate data to assign another value. The RSC default is effectively an additional safety factor on the RfD. RSCs are not used in the risk calculations for carcinogenic chemicals where incremental risk is the metric.² Liter-equivalent values are sometimes used, especially for volatile organic compounds (VOCs) where exposure contributions for inhalation and dermal exposure from bathing and showering may be incorporated in arriving at a benchmark drinking water value.

Some further caution is warranted when using guidelines developed in other countries. Some Australian guidelines, which were established using a screening methodology referred to as the "threshold of toxicological concern" (TTC), are an example. This methodology may be used only with chemicals for which there is very limited toxicological data. Its application results in values that can be 1 to 2 orders of magnitude lower than would be derived by evaluating existing data on the same chemical. This can be illustrated by comparing the ADI for caffeine developed by Health Canada based on a very large human data base, which stated that 300 milligrams (mg) of caffeine per day is acceptable in women of childbearing age (Nawrot et al., 2003), to the 350 micrograms per liter (μ g/L) value in the Australian guidelines that was based on the TTC methodology (NRMMC-EPMC-NHMRC, 2008). As long as these inherent differences are recognized and clearly distinguished from one another where need be, the Panel is comfortable with the use of guidelines from the above sources as described.

Several doses with *de minimis* risk have been derived for drugs (pharmaceuticals) that were also proposed as benchmarks in the Strawman. Although these are commonly used in judging doses that can be used safely in therapeutics, the bases for these RfDs are quite different and cannot be used interchangeably with the more official benchmarks described above, as suggested in the Strawman. Their main advantage is that they are always based upon clinical experience in humans, and the data are frequently derived from controlled clinical trials. Two of these RfDs,

² Note: It is not logical to apply an RSC for drugs in drinking water as an extremely small allocation to drinking water would result. The amount of the drug from water contributes virtually nothing to the therapeutic dose.

the MRTD and maximum recommended daily doses (MRDD), have been developed within a therapeutic setting where toxicity and adverse effects are considered in the context of the therapeutic benefit. The values are derived from a standard text (Martindale, 2011). However, values are available on a U.S. FDA website.³ The definition provided for these constructs are:

"The MRTD of a pharmaceutical is an estimated upper dose limit beyond which a drug's efficacy is not increased and/or undesirable adverse effects begin to outweigh beneficial effects."

"The maximum recommended daily dose for pharmaceuticals (MRDD) is empirically derived from human clinical trials. The MRDD is an estimated upper dose limit beyond which a drug's efficacy is not increased and/or undesirable adverse effects begin to outweigh beneficial effects. The MRDD is similar to the MRTD except that it is meant to identify the safe starting dose for clinical studies."

Conceptually, the MRTD and MRDDs are not derived in a way that is equivalent to that used in arriving at safe exposures in drinking water by the U.S. EPA (e.g., in HAs). The MRTD database generally includes people exposed over a limited portion of their lifetime (3 to 12 months, the general duration of clinical trials). It only addresses the patient population being treated (e.g., teratogenic effects of the statins would not be considered in the treated population, but there would be a caution that they should not be used in women of child-bearing age). Truly chronic outcomes, such as cancer, may not be given the weight they are assigned in the development of MCLs (e.g., a higher risk level would be accepted in consideration of a likely therapeutic benefit).

The lowest therapeutic dose as a benchmark for estimating "safe levels" for pharmaceuticals in drinking water is a different construct. The adverse effects that are identified in standard texts may be based upon clinical trials. If so, good incidence data may be available for these effects. However, adverse drug reactions that have been reported over the history of the drug's therapeutic use form a substantial portion of the assembled database. As emphasized in Bull et al. (2011), the nature of these side effects needs to be taken into account when assigning additional uncertainty factors. Several publications (e.g., Physicians' Desk Reference, Drug Information Handbook, Facts and Comparisons) are based primarily upon the U.S. FDA database on drugs in use, but do provide some evaluation of the primary literature. Bull et al. (2011) proposed that the lowest therapeutic dose be considered the equivalent of a Lowest Observed Adverse Effect Level (LOAEL) and that appropriate uncertainty factors be applied to adjust for the frequency and severity of the adverse effects associated with the drug's use. This literature also specifically identifies drugs that have been shown to be developmental toxicants in animals, as well as humans. It identifies the adverse effects of compounds with some summary evaluation of the strength of evidence. As a LOAEL taken from human studies, uncertainty factors as low as 100 could be applied, but greater uncertainty factors should be applied to adjust for drugs with short-term clinical courses (usually the case with antibiotics and antimicrobials), and those identified as teratogens or developmental toxicants. Those compounds identified as carcinogens should be assessed using linear extrapolation, if the data are available. If not, it has been suggested that dividing the lowest therapeutic dose by 500,000 (Bull et al., 2011) would

³ <u>http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm092199.htm.</u>

produce a cancer risk estimate at approximately the 10⁻⁶ lifetime risk (this assumes that the lowest therapeutic dose might have produced a 50-percent response, which is a conservative assumption because with the exception of chemotherapeutic agents, most often cancer data are from animals and the doses in cancer studies in animals are generally higher than the therapeutic dose).

Finally, there are methods to establish a TTC for chemicals that have no data related to adverse health effects. These methods are most commonly applied in determining whether minor contaminants of a commercial product require toxicological testing or not. They are based upon the statistical evaluation of a large groups of chemicals with similar structure and functional groups to identify a 95-percent lower confidence level for chronic no adverse effect level and then applying uncertainty factors as one would do for non-cancer risk assessment. Certain chemical classes are excluded from this type of analysis (e.g., nitrosamines, endocrine active compounds, etc.). If the chemical occurs below the threshold value for chemicals that are not excluded from this process, it does not require further characterization. Therefore, values derived by this process should not be identified as guidelines, but as TTC-derived values. It is almost certain that a TCC-derived value for a chemical will be 1 to 2 orders of magnitude below a guideline for the same chemical derived from actual data, if it were available.

As discussed above, there are many chemicals that occur in municipal wastewater at concentrations far below those that are of health concern. These chemicals can be useful for more systematically characterizing the effectiveness of the treatment train. Drinking water MCLs have not been developed for these chemicals largely because that would mandate expensive monitoring programs that are costly. Further, these chemicals have not been identified in drinking water at concentrations of health concern. In the evaluation of treatment trains, it will be convenient to establish a guideline for these chemicals that would approximate a regulatory concentration, simply to establish that they do not occur at concentrations that are of health concern.

In Table 2, the Panel provides a summary of conclusions relative to the use of these various secondary sources for data appropriate for the development of guidelines that would identify levels more or less consistent with MCLs.

The draft WRRF report prepared by Trussell Technologies used the term "Risk-Based Action Level" (RBAL) for what is essentially correcting the amount in drinking water with a default calculation of the relative source contribution (RSC) for water. However, the RSC calculation is only used with non-carcinogens or non-carcinogenic endpoints. Also, risks are only calculated for carcinogens. The effects of non-carcinogens are considered to have thresholds, so there is no-risk at the MCLG with some margin of safety. RSC calculations are not used for carcinogens as the risk is added to the background, which would include occurrences of the carcinogen under consideration in other media. Therefore, this term is used in a somewhat different way than is used in arriving at MCLGs and MCLs.

Benchmark	Appropriate to Adjust with the RBAL ^b Calculation	Comments
Reference dose	Yes	Not for carcinogens ^d
Minimal risk levels	Yes	
Acceptable daily intake	Yes	Not for carcinogens ^d
Acceptable daily dose	Yes	Not for carcinogens ^d
Long-term health advisory	Included ^c	Not for carcinogens ^d
Predicted no-effect concentration	Yes	Not for carcinogens ^d
Maximum recommended therapeutic dose	No	Requires additional uncertainty factors
Maximum recommended daily dose	No	Requires additional uncertainty factors
Minimum oral therapeutic dose	No	Requires additional uncertainty factors
Maximum tolerated dose	No	Can be used with very large uncertainty factors
Australian drinking water guidelines	Usually	Must consider basis of value
Lowest guideline value	Included ^c	Includes MCL/MCLGs, and HAs
Lower confidence interval of a daily dose that would produce a 10-percent increase in cancer incidence	No	Could be used with appropriately large uncertainty factor of 740,000 (Gaylor and Swirskey- Gold, 1998)
Provisional guideline value	Yes	
Monitoring trigger level	No	Basis not clear
Drinking water equivalent level (based on lowest therapeutic dose)	No	Requires additional uncertainty factor based on the nature and severity of reported side effects; the drinking water equivalent level in this publication equals the lowest therapeutic dose
Pharmaceutical ADI	Yes	Only if has been derived from toxicological data in a way that is consistent with other ADIs

Table 2. Evaluation of *De Minimis* Risk Benchmarks^a

^a The list is not ordered by preference. In addition, the Panel notes that reservations exist for the use of the RBAL calculation for these "benchmarks."

 b RBAL = Risk-based action level.

^c RBAL is accounted for by the relative source contribution (RSC) for these guidelines. ^d Carcinogen levels are calculated as added lifetime risk with no threshold. As a result, the RSC calculation is not applied since alternate sources are included in the background risk.

2.3.3 Selection of Chemical Parameters as Health-Related Criteria for Treatment Train Evaluation

Selecting chemicals as benchmarks for evaluating the efficacy of treatment trains within a fullscale treatment facility should focus upon certain key factors, including the following:

- In actual application, treatment trains will have to be capable of producing water that meets all published guideline or HA levels.
- Contaminants/parameters used for establishing performance must occur within the source water at a high frequency and at sufficient concentrations to allow for a large dynamic range for evaluating treatment trains.
- Appropriately sensitive and specific analytical methods.
- A diversity of contaminants that are broadly representative of the varying types of contaminants of health concern that could be present in wastewater.
- An array of contaminants that broadly represent differing properties of contaminants that affect their removal by various unit processes within a treatment train.
- Ideally, real-time online monitoring potential.

Contaminants of recognized health concern occur commonly in wastewater, and some may be found at high concentrations. Many contaminants in this group have guideline values or standards. Therefore, comparisons to drinking water standards and other health-related guidelines (e.g., U.S. EPA HAs or Health Reference Levels [HRLs]) must be part of any evaluation of treatment trains using wastewater as a source. On the other hand, most contaminants within this group will not occur in raw sewage or finished water at concentrations sufficiently above the sensitivity of the analytical methods available to provide for robust evaluations of performance.

Some regulated chemicals result from treatment, and the impact of these treatments on the final product water must be evaluated. The DBPs are the principal class that falls within this group. The nature and concentrations of the DBPs will vary with the type(s) of disinfection used in the treatment train and applied technologies. Frequently, more than one disinfectant is used within a treatment train. Therefore, DBPs selected for assessment need to include chemicals typical of the disinfectant(s) being used in the system.

Some regulated chemicals (e.g., selected pesticides and herbicides) can occur in drinking water, but usually not at concentrations above the MCL. If these are observed in the wastewater source, it will be important to document their removal. However, these chemicals are unlikely to routinely occur at concentrations that contribute to significant health risk from the treated water or that would be useful for establishing the removal efficiencies of treatment trains.

Numerous contaminants occur frequently in reclaimed water, but generally at concentrations several orders of magnitude below those of health concern. To the extent that the concentrations of these contaminants are substantially greater than the sensitivity of methods that are used in their analysis, they provide a very useful tool for evaluating treatment train performance. Pharmaceuticals and personal care product ingredients have been studied extensively in wastewater and drinking water, and many occur quite commonly (especially in wastewater),

albeit at very low concentrations. Several of these have been suggested as surrogates/indicators of the performance of water treatment.

Additional chemicals are suggested primarily because they can be measured with the same methods. Thus, they add little to the cost of the analysis. In most circumstances, the inclusion of these compounds can improve the robustness of the evaluation of treatment train performance. For example, information can be collected on perchlorate using the same method used for the analysis of bromate and chlorate. Perchlorate is not likely to occur at concentrations of significance to health in most wastewaters, so it is not suggested as a parameter that will be broadly useful for the evaluation of treatment trains, but if it happens to be present well above detection limits, having that removal information will be useful.

Finally, there are several general surrogate parameters that provide useful information on the functioning of processes and their continuing performance for removing many chemicals and microbials. These include total organic carbon (TOC), conductivity, and perhaps some spectroscopic measurements. These techniques are sensitive, and many of them are amenable to real-time online application for process control.

The main objective of this work is to ascertain treatment efficiencies for alternative treatment trains and to develop a framework for determining the criteria to protect public health, not to demonstrate regulatory compliance. Judgments need to be made as to which of the listed chemicals need to be included in the testing, and the appropriate locations in the treatment train and frequency of sampling necessary to satisfy that goal.

2.3.4 Disinfection Byproducts

Treatment trains that generate excessive amounts of DBPs not readily removed by subsequent unit processes are not acceptable. Therefore, they should be monitored in the final product water to ensure that the byproducts do not exceed guidelines (Table 3). It may be necessary to monitor levels following different unit processes so that modifications can be made to bring the train into compliance with current standards.

Chemical Name	Criterion	Rationale	Source
THMs	80 μg/L	Prominent chlorination byproducts	U.S. EPA MCL
HAA5	60 µg/L	Polar group of chlorination byproducts	U.S. EPA MCL
NDMA	10 ng/L	Byproduct of chloramination	CDPH notification level
Bromate	10 µg/L	Byproduct of ozonation	U.S. EPA MCL/WHO guideline
Chlorate	800 μg/L	Reflective of hypochlorite use	CDPH notification level

 Table 3. Disinfection Byproducts that Should Be Measured in the Evaluation of Treatment Trains

Trihalomethanes (THMs). The four regulated THMs include chloroform, bromodichloromethane, dibromochloromethane, and bromoform. The current MCL of 0.080 milligrams per liter (mg/L) is the sum of the four individual THMs in any combination. They are major components among the many chlorinated/brominated DBPs formed from reactions of primarily natural organic carbon components with chlorine and hypochlorite. The brominated species are produced when bromide is also present. The intent of the regulation was to use the THMs as readily measured indicators so that processes that reduce THM formation may reduce concentrations of some other unregulated byproducts of chlorination.

Halogenated acetic acids. The five regulated haloacetic acids (HAAs) include: chloroacetic acid, dichloroacetic acid, trichloroacetic acid, bromoacetic acid, and dibromoacetic acid. The current MCL of 0.060 mg/L is the sum of the five individual HAAs (HAA5) in any combination. Special attention should be paid to the dihaloacetic acids. Bromochloroacetic acid has now also been demonstrated as a multispecies, multi-organ carcinogen (NTP, 2009). Preliminary National Toxicology Program (NTP, 2012) reports indicate that bromodichloroacetic acid is also carcinogenic in mice (rat data are not yet posted). Simple inclusion of these two compounds within the HAA group will undoubtedly affect the MCL in the future. Like THMs, they are major components among the many chlorinated/brominated DBPs formed from the reactions of natural organic carbon components with chlorine and hypochlorite.

NDMA (N-Nitrosodimethylamine). The major source of NDMA in water is as a byproduct of chloramine use when wastewaters contain nitrogenous precursor chemicals such as dimethylamine. NDMA can be detected in parts per trillion concentrations. Other nitrosamines can also be produced by the same processes, but their precursors are much less evident in wastewaters so NDMA is the predominant nitrosamine found in wastewater-impacted waters. NDMA is not efficiently removed by RO because of its low molecular weight. It is reactive to UV light and has significant absorption maxima at 228 nanometers (nm) and 332 nm. However, the low-pressure lamps commonly used in water treatment have dominant UV emissions at 254 nm, but some NDMA direct photolysis occurs under those conditions. Medium-pressure lamps are more effective because they produce a broader range of wavelengths. The State of California has a notification level of 10 nanograms per liter (ng/L) and a PHG of 3 ng/L for NDMA. The Unregulated Contaminants Monitoring Rule (UCMR2) specifies a minimum reporting level of 2 ng/L for NDMA (Russell et al., 2012). It is probable that a future U.S. EPA MCL will be in the range of the California notification level.

Bromate. Bromate is present in hypochlorite as a byproduct of the electrolysis of sodium chloride salt when some bromide is present in the salt. It is also produced in water from ozone oxidation of bromide. The current MCL is $10 \mu g/L$.

Chlorate. The presence of chlorate in water is primarily from the use of aged hypochlorite solutions for disinfection at any point in the treatment train. Storage time, concentration, pH, and temperature of the stored hypochlorite solutions are important contributing factors. Chlorine dioxide also produces chlorate in water, and ozone will oxidize hypochlorite to chlorate if it is applied to water containing residual hypochlorite. A lesser source is from source surface water subjected to upstream discharges from paper mills. Concentrations of chlorate in the mg/L range are possible if operators are not aware of the importance of age and storage conditions of their

hypochlorite disinfectant. The U.S. EPA HRL for chlorate is 210 μ g/L, but that was based upon 20-percent RSC, which was applied to all HRL calculations. A more realistic RSC of 80 percent as used by Canada, and WHO would make the value 840 μ g/L. Chlorate is on the new U.S. EPA Contaminant Candidate List (CCL), and it is likely to be regulated in the future. CDPH has a notification level for chlorate of 800 μ g/L.

2.3.5 Chemicals of Potential Health Concern that May Occur in Source Wastewater

There are a variety of chemicals that could occur in wastewater and are not regulated in drinking water that should be looked for in the source wastewater and, if detected, in the product water (Table 4). Most of these will occur in wastewater in concentrations too close to the analytical detection limit to be useful in evaluating the efficiency of treatment train performance. Some of those that are not specifically regulated in drinking water will be detected and can be measured with analytical methods applied to other recommended surrogates/indicators, so information on their removal can be gained without significant additional cost. The measurement of the unregulated chemicals on this list throughout the treatment train should be considered optional.

Chemicals	Criterion/ If Applicable	Rationale	Source
PFOA	0.4 µg/L	Known to occur, frequency unknown	Provisional short- term U.S. EPA HA
PFOS	0.2 µg/L	Known to occur, frequency unknown	Provisional short- term U.S. EPA HA
Perchlorate	15 μg/L 6 μg/L	Of interest, same analysis as chlorate and bromate	U.S. EPA HA California MCL
1,4-Dioxane	1 μg/L	Occurs at a relatively low frequency in wastewater, but variable and incomplete removal by RO membranes	CDPH notification level
Steroid Hormones			
Ethinyl Estradiol	None, but if established, it will approach detection limit (low ng/L).	Should evaluate presence in source water	Bull et al. (2011)
17-β-Estradiol	None, but if established, it will approach detection limit (low ng/L).	Should evaluate presence in source water	Bull et al. (2011)

Table 4. Non-Regulated Chemicals of Interest from the Standpoint
of Public Health (If They Are Present in Wastewater)

Perchlorate. Perchlorate can be present at low $\mu g/L$ levels in some source waters due to natural or anthropogenic processes. Perchlorate also forms in aged hypochlorite solution secondary to chlorate production during storage. Perchlorate is unlikely to be a problem unique to wastewater sources used for potable reuse and would not be expected at concentrations that would allow for a robust assessment of treatment trains. However, its analysis is the same as that for bromate and chlorate, and the data can be collected at little additional cost if it happens to occur. The current U.S. EPA HA is 15 $\mu g/L$. The California MCL is 6 $\mu g/L$.

Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS). Both are polyfluorinated C₈ organic acids. PFOA is an industrial chemical whose predominant use is in the emulsion polymerization of tetrafluoroethylene. It has both oil and water repellant properties and has been used in several consumer products, but the extent of exposure from the various sources is not well understood. PFOS has properties similar to PFOA and is both hydrophobic and lipophobic. It was the key ingredient in ScotchguardTM, among many other applications. Neither PFOA nor PFOS is readily biodegraded, but RO should be effective in the removal of both compounds from water. These compounds could be useful in evaluating treatment trains if they occur in wastewater at a high frequency and at sufficient concentrations to allow effective characterization of removal. The U.S. EPA (2009) has published a provisional short-term HA for PFOA of 0.4 μ g/L and for PFOS of 0.2 μ g/L.

1,4-Dioxane. 1,4-Dioxane (C₄H₈O₂) is an organic solvent with numerous industrial and synthetic uses. It is highly water soluble and environmentally stable, but it is oxidizable by free radical chemical processes and slowly by UV. When found in water, it is at μ g/L levels. Its low molecular weight and chemical properties render it inefficiently removed by RO; advanced oxidation processes (AOP) that generate hydroxyl radicals are able to substantially remove it, depending upon the dosages that are applied. Pretreatment and discharge controls are the best ways to prevent its presence in wastewater intended for reuse. It does not occur with sufficient frequency and concentrations to be useful in evaluating treatment trains. If present in a particular water source at concentrations well above the detection limit, it could be useful. The U.S. EPA current 10⁻⁶ lifetime risk value for 1,4-dioxane is 0.35 µg/L and the noncancer lifetime HA is 200 µg/L based upon non-cancer effects (U.S. EPA, 2012), but CDPH has posted a notification level of 1 µg/L based upon an evaluation of new evidence of its carcinogenic activity in animals and the limits of the current standard analytical detection limit.

Ethinyl Estradiol and 17-β-Estradiol. These steroid hormones are very active estrogenic substances that have been reported in various wastewater-impacted source waters and wastewater in the past. The concentrations that have been observed more recently are far below those originally reported, and the original data are thought to have been complicated by contamination during sampling and analysis. Nevertheless, they may occasionally be observed in the low ng/L range and are the most potent of the estrogenic compounds that routinely are introduced into sewage flows. Guidance values, if they are to be established in the future, would be in the low ng/L range. Therefore, it is necessary to ensure that these compounds are not present in the wastewater source and, if they are, ensure that they are removed. Estrone, which occurs at higher concentrations, is suggested below as a surrogate for evaluating the removal of a variety of steroid hormones by treatment trains (including androgens, corticosteroids, and mineral corticoids commonly used in medicine).

2.3.6 Chemicals Known to Occur and Useful in Evaluation of Treatment Trains

In the opinion of the Panel, the chemicals shown in Table 5 are considered useful for evaluating the effectiveness of alternative treatment trains. These compounds are detected at a high frequency and at sufficiently high concentrations relative to their detection limits to make them useful measures of the removal of health-significant organic chemicals with a variety of structures and varying physical chemical properties. The Panel does not intend to suggest that all of these chemicals should be measured. Instead, the Panel is suggesting the need for selecting compounds of varying chemical/physical properties within the suite used to evaluate treatment trains. Where chemicals are similar enough to substitute for one another, the Panel listed them in a preferred order in Table 5. Therefore, if the concentration of the first choice is too low, the study can employ one of the alternatives. In general, these compounds can be measured by the same chemical methods used for other chemicals, so switching from one to the other as the key parameter because the frequency of occurrence is unreliable or the concentration of the first choice is too low will generally result in little added analytical cost.

Pharmaceuticals/Drugs and Antibiotics and their metabolites may be present in wastewaters predominantly due to excretion resulting from therapeutic uses in humans. Some may be due to the improper disposal of drugs by consumers, or from upstream surface discharges from animal feedlots. Many of these chemicals are degraded in the environment, but some survive at ~ng/L concentrations in water. Many are reactive with oxidants like chlorine and ozone in water treatment. Most remaining residues are removed by RO, AOP, or soil aquifer treatment (SAT), but a few have been found in finished water at trace ng/L levels. Chemicals should be selected to represent a variety of chemical properties. Generally speaking, there are alternatives that can be measured by the same method if the identified chemicals do not occur in a given source of wastewater. An example of a suite of drugs that have varying physical chemical properties is as follows:

<u>Cotinine</u> - Suggested because it is a low molecular weight nitrogen-containing heterocyclic compound that should be partially charged at pHs encountered/employed in water treatment. It may be removed by a variety of processes. Cotinine occurs ubiquitously in sewage, but concentrations may be too low for treatment train evaluation. If the latter case, primidone, phenyltoin, or caffeine would be acceptable substitutes.

<u>Meprobamate</u> - A low molecular weight chemical that contains one amine carbon and a carbamate. The basic structure is alkane-like. Meprobamate occurs ubiquitously and generally in adequate concentrations for the evaluation of treatment trains. If concentrations are low, atenolol would be an acceptable substitute.

<u>Carbamazepine</u> - A low molecular weight tricyclic heterocyclic compound with an extracylic carbamate group. Its seven-member ring is susceptible to attack by chlorine. It is almost ubiquitous in wastewaters and occurs at sufficient concentrations to allow the robust evaluation of treatment trains. There are unpublished data suggesting that it is carcinogenic in rats and mice at a dose of 25 mg/kg per day. Bruce et al. (2010) calculated a 10^{-6} added lifetime risk at 12 µg/L based upon the method suggested by Gaylor and Swirskey-Gold (1998). The Panel rounded this number down to 10 µg/L.

<u>Estrone</u> - A natural steroid hormone that occurs at substantially greater concentrations in wastewater than 17- β -estradiol or ethinyl estradiol (usually present at or below detection limits). Therefore, it is much better suited for documenting treatment train performance than the more active estrogens and androgens.

Pharmaceuticals	Criterion ^a /If Applicable	Rationale	Source
Cotinine/Primidone/ Phenyltoin	1/10/2 µg/L	Surrogate for low molecular weight partially charged cyclics	Bruce et al. 2010; Bull et al. (2011)
Meprobamate/Atenolol	200/4 µg/L	Occur frequently at ng level	Bull et al. (2011)
Carbamazepine	10 µg/L	Unique structure	Bruce et al. (2010)
Estrone	320 ng/L	Surrogate for steroids	Based on increased risk of stroke and deep vein thrombosis in women taking the lowest dose (0.625 mg per day) of conjugated estrogens/1,000 ^b
Other Chemicals			
Sucralose	150 mg/L ^c	Surrogate for water soluble, uncharged chemicals, moderate molecular weight	CFR Title 21, revised April 1, 2012 ^d
ТСЕР	5 µg/L	Chemical of interest	Minnesota Dept. of Health (2011) guidance value
DEET	200 µg/L	Common constituent in highly treated wastewaters	Minnesota Dept. of Health (2011) guidance value
Triclosan	2,100 µg/L	Chemical of interest	Risk-based action level (NRC, 2012)

 Table 5. Chemicals of Potential Health Concern that Should Be Useful

 for Evaluating Effectiveness of Organic Chemical Removals by Treatment Trains

^a In the case of pharmaceuticals, the criterion is given as the drinking water equivalent concentration for the lowest therapeutic dose/1,000. In the case of the anticonvulsant drugs, the lowest daily maintenance dose in adults/10,000 was used in recognition of the teratogenic potential of these drugs (primidone). However, the numbers for carbamazepine and phenyltoin are based on reported carcinogenicity.

^c Sucralose based upon ADI established by the U.S. FDA of 5 milligrams per kilogram (mg/kg) per day \times 60 kg/2 L.

^dCode of Federal Regulations <u>http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR</u>

^bConjugated estrogens (largely estrone conjugates) administered without progestin increased the risk of deep vein thrombosis and stroke significantly in a large clinical study of postmenopausal women conducted over 5.1 years (involved groups >5,000 treated and 5,000 placebo subjects). Cited in RxList (2012).

Sucralose is a chlorinated derivative of sucrose that is used as an artificial sweetener approved for use in food by the U.S. FDA. As a saccharide derivative, it is water soluble, but carries no charge. It is not readily biodegradable, and it is usually present in wastewater at concentrations well above the detection limit or level of concern.

TCEP (tris[2-chloroethyl]phosphate) is an organophosphate ester that is used as a fire retardant. It should not be confused with the reducing agent for which the same acronym is used. The State of Minnesota has a chronic guidance of 200 μ g/L and a guidance for cancer of 5 μ g/L.

Triclosan is a biocide used in numerous consumer products, such as toothpaste at 0.3 percent (~3,000 parts per million). It is a dichlorophenylchlorophenoxy ether, and its molecular weight is 289.5 Daltons. It is partially degradable during wastewater treatment and in the environment. Its chemical structure indicates that it would be reactive with disinfectants like chlorine and ozone, and removed by adsorption and RO. It is commonly found in wastewater and often in highly treated wastewaters at μ g/L levels. The U.S. EPA HRL for triclosan is 2,100 μ g/L.

DEET (N,N-diethyl-meta-toluamide) is a common insect repellant in lotions and creams applied to the skin. Its molecular weight is 191.3 Daltons. It should be biodegradable and would be expected to be removed from water by adsorption and RO, although it is commonly detected at μ g/L levels in highly treated wastewaters. The State of Minnesota has a chronic guidance value of 200 μ g/L.

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APPENDIX A: NWRI INDEPENDENT ADVISORY PANEL MEMBERS

JAMES CROOK, PH.D., P.E. (PANEL CHAIR)

Environmental Engineering Consultant (Boston, Massachusetts)

Jim Crook is an environmental engineer with more than 35 years of experience in state government and consulting engineering arenas, serving public and private sectors in the U.S. and abroad. He has authored more than 100 publications and is an internationally recognized expert in water reclamation and reuse. He has been involved in numerous projects and research activities involving public health, regulations and permitting, water quality, risk assessment, treatment technology, and all facets of water reuse. Crook spent 15 years directing the California Department of Health Services' water reuse program, during which time he developed California's first comprehensive water reuse criteria. He also spent 15 years with consulting firms overseeing water reuse activities and is now an independent consultant specializing in water reuse. He currently serves on several advisory panels and committees sponsored by NWRI and others. Among his honors, he was selected as the American Academy of Environmental Engineers' 2002 Kappe Lecturer and the WateReuse Association's 2005 Person of the Year. Crook received a B.S. in Civil Engineering from the University of Massachusetts and both an M.S. and Ph.D. in Environmental Engineering from the University of Cincinnati.

RICHARD BULL, PH.D.

Consulting Toxicologist MoBull Consulting (Richland, Washington)

Since 2000, Richard Bull has been a Consulting Toxicologist with MoBull Consulting, where he conducts studies on the chemical problems encountered in water for water utilities, as well as federal, state, and local governments. Bull is a Professor Emeritus at Washington State University, where he maintains Adjunct Professor appointments in the College of Pharmacy and the Department of Environmental Science. Formerly, he served as a senior staff scientist at DOE's Pacific Northwest National Laboratory, Professor of Pharmacology/Toxicology at Washington State University, and Director of the Toxicology and Microbiology Division in the Cincinnati Laboratories for the U.S. Environmental Protection Agency. Bull has published extensively on research on central nervous system effects of heavy metals, the carcinogenic and toxicological effects of disinfectants and disinfection byproducts, halogenated solvents, acrylamide, and other contaminants of drinking water. He has also served on many international scientific committees convened by the National Academy of Sciences, World Health Organization, and International Agency for Research on Cancer regarding various contaminants of drinking water. Bull received a B.S. in Pharmacy from the University of Washington and a Ph.D. in Pharmacology from the University of California, San Francisco.

JOSEPH A. COTRUVO, PH.D.

President Joseph Cotruvo & Associates, LLC (Washington, D.C.)

Joe Cotruvo is President of Joseph Cotruvo & Associates, an environmental and public health consulting firm, and is active in the World Health Organization (WHO)/NSF International Collaborating Centre for Drinking Water Safety and Treatment. Previously, he served as Director of the Criteria and Standards Division of the U.S. Environmental Protection Agency (U.S. EPA) Office of Drinking Water, where he developed the *Drinking Water Health Advisory System* and numerous *National Drinking Water-Quality Standards and Guidelines*. He was also Director of the U.S. EPA's Risk Assessment Division and a former Vice President at NSF International. At present, Cotruvo is a member of WHO Drinking Water Guidelines development committees and he has led the recently published monograph on *Desalination Technology: Health and Environmental Aspects*. He is also leading studies on bromate metabolism through the American Water Works Association Research Foundation and on recycled water contaminants for the WateReuse Foundation. He is chairman of the Water Quality and Water Services Committee of the Board of Directors of the District of Columbia Water and Sewer Authority. Cotruvo received a B.S. in Chemistry from the University of Toledo and a Ph.D. in Physical Organic Chemistry from Ohio State University.

HARVEY F. COLLINS, PH.D., P.E.

Environmental Engineer Consultant (Sacramento, California)

Harvey Collins has over 30 years of experience in California state government, working in all fields of sanitary/environmental engineering and environmental health. He served as Deputy Director of Public Health at the California Department of Health Services, and was Chief of the Division of Drinking Water and Environmental Management when he retired in 1995. Since then, he has consulted on various water and wastewater engineering projects and has served on several blue ribbon panels. He also has received numerous awards, including a Rudolf Hering Medal of the American Society of Civil Engineers, Walter F. Snyder Award from the National Environmental Health Association and NSF International, and Special Recognition Award from the California Department of Health Services. Collins received a B.S. in Civil Engineering from Oregon State University, an M.S. in Sanitary Engineering from the University of Missouri, Columbia, and a Ph.D. in Sanitary Engineering from the University of California, Berkeley. He is a licensed Civil Engineer in the State of California.

WALTER JAKUBOWSKI

Consultant WaltJay Consulting (Spokane, Washington)

Walter Jakubowski has degrees in Pharmacy from Brooklyn College of Pharmacy, Long Island University; in microbiology from Oregon State University, and graduate training in epidemiology from the University of Minnesota. He has research publications on hospital pharmacy; on microorganisms in oysters and clams under the federal Shellfish Sanitation Program, and more than 40 peer-reviewed publications on determining the health effects and public health significance of pathogens, especially intestinal protozoa and viruses, in drinking water, waste water and municipal sewage sludge. He has served as a consultant to the World Health Organization on pathogenic intestinal protozoa (for development of the International Drinking Water Guidelines), and to the Pan-American Health Organization on environmental virus methods. He was instrumental in conducting the first international symposium on Legionella and Legionnaire's Disease at the Centers for Disease Control. He has more than 48 years of experience working with waterborne pathogens, especially enteric viruses, Giardia and Cryptosporidium. He initiated landmark studies on the human infectious dose of Cryptosporidium and chaired the Joint Task Group on Pathogenic Intestinal Protozoa for Standard Methods for the Examination of Water and Waste Water from 1978 to 2005. He was a charter member of U.S. EPA's Pathogen Equivalency Committee and served on that committee until his retirement from the U.S. Public Health Service/Environmental Protection Agency in 1997. Since then, he has been practicing as a private consultant while serving on various professional committees, panels, and boards.



Panel Members: (top left) Richard Bull and Harvey Collins; (bottom left) Joseph Cotruvo, James Crook, and Walter Jakubowski.

NATIONAL WATER RESEARCH INSTITUTE Independent Advisory Panel Meeting

Workshop on Examining the Criteria for Direct Potable Reuse (Trussell Technologies Project – WRRF 11-02)

Workshop Agenda Wednesday, August 29, 2012

Location:

Los Angeles Department of Water & Power Central Power Yard Conference Room (3rd Floor) 1350 South Wall Street Los Angeles, CA 90015 **On-site Contact:**

Jeff Mosher, NWRI (714) 705-3722 (cell)

Time	Торіс	Presenter
7:30 a.m.	Continental Breakfast	
8:15 a.m.	Welcome	Jim McDaniels (Los Angeles Department of Water and Power)
8:20 a.m.	Panel Introductions	Jeff Mosher (NWRI)
	Attendee Introductions	Jim Crook (Panel Chair)
	Review Panel Process	
	Review Agenda	
8:30 a.m.	Design and Operational Criteria for Big Springs	David Sloan (Freese and Nichols)
9:05 a.m.	Questions	
9:20 a.m.	Design and Operational Criteria Overseas	Ian Law (IBL Solutions)
10:00 a.m.	Questions	
10:15 a.m.	Break	

Time	Торіс	Presenter
10:30 a.m.	Technology Review	Shane Trussell (Trussell Technologies)
11:10 a.m.	Questions	
11:25 a.m.	National Research Council "Water Reuse" Report	Shane Snyder (University of Arizona)
12:05 p.m.	Questions	
12:20 p.m.	Working Lunch	
1:20 p.m.	Path Forward	George Tchobanoglous (University of California, Davis)
1:50 p.m.	Questions	
2:05 p.m.	Strawman – Proposed Criteria	Rhodes Trussell (Trussell Technologies)
2:45 p.m.	Questions	
3:00 p.m.	Break	
3:15 p.m.	Public Health Perspective	Bob Hultquist (California Department of Public Health)
3:45 p.m.	Questions	
4:00 p.m.	Open Discussion	
4:25 p.m.	Workshop Adjourns	

NATIONAL WATER RESEARCH INSTITUTE Independent Advisory Panel Meeting

Criteria for Direct Potable Reuse (WRRF 11-02)

August 30, 2012

Los Angeles Department of Water and Power Los Angeles, CA

Preliminary Agenda

Charge:

Develop criteria that are protective of public health to evaluate treatment technologies for Direct Potable Reuse

Meeting Objectives:

- Review the draft literature review prepared by the project team and information presented at the August 29, 2012 Workshop.
- Comment on proposed criteria of pathogens, including: pathogen selection, removal goals, removal criteria, level of acceptable risk, need for multiple barriers, and use of indicators and surrogates.
- Comment on proposed criteria for chemical contaminants, including: current regulated contaminants, unregulated compounds, acceptable risk, and use of indicators and surrogates.
- Comment on the need for criteria for related topics such as monitoring, operations and maintenance; treatment reliability and redundancy, engineered buffer and time to react, and public perception.
- Develop an outline for Panel Report.

Time	Торіс	Presenter
8:00 am	 Welcome and Introduction Introductions Overview of charge Review panel process Review agenda 	Jeff Mosher (NWRI) Jim Crook (Panel Chair)
8:15 am	Review information presented at the workshop and the draft literature review prepared by the project team	Jim Crook (Panel Chair); Rhodes Trussell (Trussell)

Time	Торіс	Presenter
8:45 am	Criteria for pathogens Presentation: Strawman – Pathogens (Rhodes Trussell) Discussion Product: Final List of Pathogens with required removals 	Panel
10:15 am	BREAK	
10:30 am	 Criteria for chemicals Presentation: Free of WW Properties (Rhodes Trussell) Discussion Product: Final List of TOrCs with risk based action limits (RBALs) 	Panel
12:00 noon	Working Lunch	
12:30 pm	 The need for other criteria Discussion Product: List of other measures that should be taken? 	Panel
1:30 p.m.	Develop report outline and initial Panel findings Next steps: Identify lead Panel member(s) for specific topics Set deadlines	Jim Crook and Panel
2:30 p.m.	Adjourn	

APPENDIX C: WORKSHOP ATTENDEES

NWRI Panel Members:

- Chair: James Crook, Ph.D., P.E., Environmental Engineering Consultant (Boston, MA)
- Richard Bull, Ph.D., MoBull Consulting (Richland, WA)
- Harvey F. Collins, Ph.D. P.E., Environmental Engineering consultant (Sacramento, CA)
- Joseph A. Cotruvo, Ph.D., Joseph Cotruvo and Associates (Washington, D.C.)
- Walter Jakubowski, WaltJay Consulting (Spokane, WA)

WateReuse Research Foundation Project Manager:

• Deana Bollaci, WateReuse Research Foundation

WateReuse Research Foundation Project Advisory Committee:

- Shankar Chellam University of Houston
- Jason Dadakis, Orange County Water District
- Jean Debroux, Kennedy/Jenks Consultants
- David Smith, WateReuse California
- David White, Bureau of Reclamation

National Water Research Institute:

- Dondra Hall, Event Manager
- Jeff Mosher, Executive Director
- Gina Vartanian, Outreach and Communications Manager

Project Team:

- Dave Hokanson, Trussell Technologies
- Brian Pecson, Trussell Technologies
- Shane Trussell, Trussell Technologies
- Rhodes Trussell, Trussell Technologies
- Andy Salveson, Carollo Engineers
- Shane Snyder, University of Arizona

Los Angeles Department of Water and Power:

- Evelyn Cortez-Davis, Manager of Water Recycling Regulatory Affairs
- Serge Haddad, Water Recycling Regulatory Group
- Paul Liu, Water Recycling Planning and Project Manager
- Jim McDaniel, Senior Assistant General Manager for Water
- Taghavi Milad, Assistant Director Water Quality Division
- Pankaj Parekh, Director Water Quality Division (on phone)
- David Pettijohn, Director of Water Resources
- Susan Rowghani, Director of Water Engineering and Technical Services
- Rosalba Santana
- Glenn Singley
- Yoshiko Tsunehara
- Jennifer Valdez

Others:

- Bob Angelotti, Upper Occoquan Service Authority
- Jorge Arroyo, Texas Water Development Board
- Hossein Ashktorab, Santa Clara Valley Water District
- John Balliew, El Paso Water Utilities
- Sadeghi Bijan, Carollo Engineers
- Patricia Bohlmann, City of Los Angeles Bureau of Sanitation
- Reid Bowman, APTwater, Inc.
- Thomas Brumett, Turner Designs
- Rajen Budhia, West Basin Municipal Water District
- Andy Campbell, Inland Empire Utilities Agency
- Guy Carpenter, Carollo Engineers
- Mickey Chaudhuri, Metropolitan Water District of Southern California
- Uzi Daniel, West Basin Municipal Water District
- Shivaji Deshmukh, West Basin Municipal Water District
- Josh Dickinson, Stanford University
- Amy Dorman, City of San Diego
- Christopher Gabelich, Metropolitan Water District of Southern California
- Monica Gasca, County Sanitation Districts of Los Angeles County
- Kevin Gomes, H2O Engineering
- Deborah Helstrom, Texas Commission of Environmental Quality
- Peter Herlihy, APTwater, Inc.
- Eric Hoek, University of California, Los Angeles
- Bob Holden, Monterey Regional Water Pollution Control Agency
- Robert Hultquist, California Department of Public Health
- Raymond Jay, Metropolitan Water District of Southern California
- Hossein Juybari, Eastern Municipal Water District
- Albert Lau, Padre Dam Municipal Water District
- Ian Law, IBL Solutions
- Sun Liang, Metropolitan Water District of Southern California
- Bruce Mansell, County Sanitation Districts of Los Angeles County
- Mike Markus, Orange County Water District
- Lenise Marreo, City of Los Angeles Bureau of Sanitation
- Robert Moncrief, H2) Engineering
- John Moreno, APTwater, Inc.
- Rich Nagel, West Basin Municipal Water District
- Jeremy Neill, The Coombs-Hopkins Company
- Seung Oh, City of Los Angeles Bureau of Sanitation
- Aleks Pisarenko, Las Vegas Valley Water District
- Marsha Pryor, Pinellas County Utilities Logan Lab (on Phone)
- Keel Robinson, Xylem
- Channah Rock, University of Arizona
- Andy Salveson, Carollo Engineers
- Arne Sandvik, Padre Dam Municipal Water District

- Terri Slifko, County Sanitation Districts of Los Angeles County
- Davis Sloan, Freese & Nichols
- Jodi Smart, GE Water
- Shahrouzeh Sneie, City of Los Angeles Bureau of Sanitation
- Shane Snyder, University of Arizona
- Kurt Souza, California Department of Public Health
- Eva Steinle-Darling, Carollo Engineers
- George Tchobanoglous, University of California, Davis
- Reymundo Trejo, Upper San Gabriel Valley Municipal Water district
- Mark Umphres, Helix Water District
- Anthony Van, City of San Diego
- Joe Walters, West Basin Municipal Water District
- Mike Wehner, Orange County Water District
- Ron Wildermuth, West Basin Municipal Water District

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