

RISK ASSESSMENT STUDY OF PPCPS IN RECYCLED WATER TO SUPPORT PUBLIC ACCEPTANCE

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Introduction

There is a growing awareness that greater public use of recycled water will be necessary to close the gap between rising demands for water and limited and/or unreliable supplies. In many communities, however, proposed water reuse projects that would be technically and economically feasible to implement are facing formidable public opposition due to perceived human health risks.

While these concerns may be unwarranted for some planned uses, studies have shown that trace concentrations of pharmaceuticals and personal care products (PPCPs) can be found in treated wastewater effluent. To best evaluate whether these residual chemicals in wastewater pose a significant threat to human health, established risk assessment methods can be employed. These methods have long been accepted by the U.S. Environmental Protection Agency (U.S. EPA) and state regulatory agencies for use in other decision-making processes that are contingent on community acceptance, such as setting residual chemical concentrations at environmental cleanup sites.

The objective of the research project WRF-09-07 is to provide quantitative human health risk assessment (HHRA) results for PPCPs in recycled water and develop a message delivery effort to present those results to the public. The risk assessment considered a range of recycled water non-potable uses, which focused on various types of agricultural and landscape irrigation. The HHRA evaluated those PPCPs frequently detected in recycled water, based on available effluent data collected throughout the U.S., with the greatest potential for adverse health effects. The HHRA applied new toxicological information with quantified exposures of typical non-potable recycled water applications to assess risks specifically associated with PPCPs in recycled water. The HHRA also assessed the relative risks from recycled water uses compared with other exposures to PPCPs. The message delivery effort makes the results of the risk assessment easily understandable and meaningful to utility management, project stakeholders and the general public. This project leveraged prior and current research projects by enabling water reuse agencies and municipalities to better respond to public opposition to recycled water projects due to perceived health risks.

The study focused specifically on PPCPs in recycled water, and does not address risks from other substances that may be present in recycled water. The study also focused exclusively on non-potable uses of recycled water.

Communicating Risk

One of the biggest hurdles to public acceptance of water reuse projects is the perception of human health risks from the use of recycled water. One way to clear that hurdle is with a robust communications

program that accurately and clearly portrays the relative human health risks of recycled water in terms that are easily understood by the public, our customers and those within our industry.

The ability for scientists to detect chemicals at very low levels has outpaced the ability to completely remove them from the environment. This has led to an increased public awareness via regional and national news reports of the presence of chemicals in our environment, including in our water and wastewater. Among the perceived health risks for recycled water projects is the presence of trace concentrations of PPCPs that can be detected in treated wastewater.

A primary goal of research project WRF-09-07 is the development of a set of educational tools to communicate the relative human health risks that PPCPs pose during routine exposure to non-potable recycled water, and how those risks compare with everyday exposure to PPCPs.

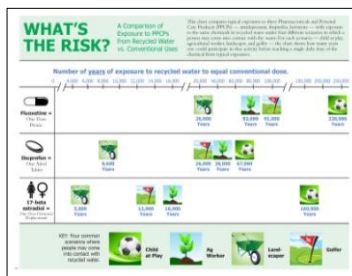
The study focused on a set of 10 PPCPs that were carefully selected to be representative of the hundreds that have been detected in recycled water and are present in commonly used products such as prescription and over-the-counter drugs, household products and food additives.

A communications strategy was developed using the risk assessment results and a series of tools were created to illustrate the relative human health risks from exposure to recycled water compared with everyday exposure to PPCPs. The tools were designed for use by utilities and agencies with recycled water projects underway or in planning stages to educate the public about the uses of recycled water and continue the public dialogue about relative health risks.

The goal was to develop materials that clearly communicate the study findings, could be easily used by utility representatives and that resonate with members of the public in a positive manner. The communications tools focus primarily on presenting the risk data in two ways: 1) comparing acceptable levels of the ten chemicals included in the study with levels typically found in recycled water, and 2) comparing the number of years of exposure to those chemicals that it would take – under various non-potable, recycled water use scenarios – for an individual to be exposed to the same single daily dose of each PPCP that one would get from typical daily activities.

Using preliminary results, the effectiveness of the overall messages and public reaction to the specific communications materials were tested in two focus groups conducted among residential water customers in Northern and Southern California. In general, the materials tested very well and the team came away with valuable feedback for refining some of the messages to increase their effectiveness. The communications tools developed, tested and refined include —

- A four-page general background piece explaining the risk assessment study and its preliminary findings, current uses of recycled water, and information about PPCPs and how the 10 chemicals were chosen for the study. The piece includes a full-page graphic illustrating the comparative risks between exposure to recycled water in the four scenarios and normal use of three products containing PPCPs.



- A fact sheet for each for the four scenarios. These fact sheets offer details about the specific exposure scenarios and also show acceptable versus actual levels of the 10 PPCPs and the number of years to reach equivalent exposures.



(1) Pharmaceuticals & Personal Care Products - PPCPs	(2) How Used/Where Found	(3) Acceptable (AT) vs. Actual Concentrations (AT)	(4) Relative Exposure at Actual Concentrations
Diapering	Over the counter (OTC) pain relievers and antibiotics are prescribed and sold in the prescription (RX) aisle.	Acceptable = 100 Actual = 1.1	The ATB will not be reached on the playground for 17,000 years before being equal to the exposure from diapering.
OTC pain relievers	Acetaminophen, ibuprofen, aspirin.	Acceptable = 1.00 Actual = 0.0004	At 100,000 years, the ATB would be equal to the exposure from use of OTC pain relievers.
Herbicides	Acetaminophen, aspirin.	Acceptable = 1.00 Actual = 0.0004	At 20,000 years, on the park, the ATB will have been equal to the exposure from the use of herbicides.
Anti-infectives	Acetaminophen, aspirin.	Acceptable = 1.00 Actual = 0.0004	At 1,000,000 years, the ATB will have been equal to the exposure from the use of anti-infectives.
OTC eye drops	Acetaminophen, aspirin.	Acceptable = 1.00 Actual = 0.0004	At 1,000,000 years, the ATB will have been equal to the exposure from the use of OTC eye drops.
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- A 12-minute video that summarizes the findings of this study, featuring interviews with scientists Laura Kennedy and Jean Debroux of Kennedy/Jenks and Mark Millan of Data Instincts. The video is intended as a self-contained educational tool that utilities can use to communicate to the public the relative risks of recycled water in an accessible format.



- A folder in which any or all of the materials listed above can be placed.

- Message points and a set of frequently asked questions on the topic of relative risk and recycled water. These will assist water utility managers and community affairs/public outreach personnel in addressing public concerns about the human health risks associated with the non-potable use of recycled water for landscape irrigation and bring a scientifically-based perspective to the discussion.

The above tools were selected for their versatility; agencies can use the folder to present the printed pieces (backgrounder and fact sheets) as a complete set. Alternately, agencies can select the pieces that best fit their situation. The team developed a video instead of a PowerPoint presentation so agency personnel would not be required to memorize presentation materials. Additionally, the video can be posted to various web sites, allowing anyone researching recycled water to click, watch and learn. The message points and frequently asked questions will be useful in addressing public queries or concerns.

It is anticipated that upon completion of the research project, the communications tools listed above will be made available to agencies through the WateReuse Research Foundation; they will foster open communications and promote informed public discussions about the relative health risks associated with the non-potable use of recycled water for irrigation purposes. It is intended that the materials, including the video, will also be made available on the WateReuse new public website: www.athirstyplanet.com.

Quantitatively Assessing Human Health Risks

To accomplish the objective of providing human health risk assessment results for PPCPs in recycled water for non-potable uses, a literature review and risk assessment was conducted for recycled water non-potable use scenarios. The risk assessment used methods established by the U.S. EPA, including a data evaluation, exposure assessment, toxicity assessment, and risk characterization.

Data Evaluation

Data obtained from literature review studies summarizing the occurrence of the PPCPs in wastewater effluent were evaluated to select the PPCPs to include in this risk assessment. The criteria for choosing the PPCPs for this project and the list of compounds are presented below. The list of PPCPs is not meant to be complete with regard to potential risk to public health, but to be representative of PPCPs in recycled water and to be useful in preparing tools that will allow the public to review PPCP issues in recycled water projects.

Four basic criteria were used to identify PPCPs for this project:

- 1) **Occurrence in recycled water.** Ideally, there exists a significant occurrence database for a candidate compound. This entails accepted, if not standardized, analytical methods, typical concentrations well above the minimum reporting level, compounds free of gross contamination and or analytical issues, and compounds that have been measured in numerous recycled waters.
- 2) **Toxicological relevance.** Although the PPCPs were not chosen solely due to their toxicological relevance, the list of compounds contains those that are currently believed to have the greatest potential human health risk for non-potable recycled water applications.
- 3) **Recognizable by the public.** To facilitate communication activities, the list contains certain compounds that are recognized by the public. Laypeople often have difficulties with complicated chemical names. Everyday products, or products in the popular press, will allow the research team to develop material that will have the greatest possibility to convey the results of the risk assessment.

- 4) **Overlap with comparable chemical risks.** When possible, compounds were chosen that occur in not only recycled water, but also in other mediums in which the general public is exposed and will be considered for comparable risk assessment (e.g., drinking water, food, and indoor and outdoor air).

It is understood that there are few PPCPs that meet all of the above criteria. The list of PPCPs was chosen in an effort to obtain a group of compounds that is present in recycled water, represents the greatest potential risk, and will allow for comparable risk assessments to the public. The 10 PPCPs chosen for this study are:

PPCP	Common usage
17-beta estradiol	Synthetic hormone
Acetaminophen	Analgesic
Bisphenol A	Various uses
Caffeine	Stimulant
<i>N,N</i> -Diethyl- <i>meta</i> -toluamide (DEET)	Insect repellent
Fluoxetine (Prozac)	Antidepressant
Ibuprofen	Non-steroidal anti-inflammatory
Perfluorooctanesulfonic acid (PFOS)	Fluorosurfactant
Sulfamethoxazole	Antibiotic
Triclosan	Antimicrobial

Exposure Assessment

According to the comprehensive statewide survey conducted by the California State Water Resources Control Board (SWRCB) in 2002, agricultural irrigation accounted for approximately 50 percent of recycled water use in California. Landscape irrigation accounted for approximately 20 percent of recycled water use. In July 2009, the SWRCB adopted general waste discharge requirements for landscape irrigation uses of recycled water (General Permit) to facilitate the regulatory process for such uses. The General Permit may result in increased landscape irrigation uses of recycled water in California.

Based on the current and anticipated volumes of recycled water for non-potable uses and the potential for human exposures, the following uses of recycled water were selected for further evaluation in the risk assessment:

- Parks, playgrounds, and school yards
- Golf courses
- Freeway, highway, and street landscaping
- Agricultural irrigation

Exposure scenarios were identified for each of these recycled water uses. The exposure scenarios represent human activities that occur and may result in exposure to recycled water. These exposure scenarios are representative of the recycled water uses selected for evaluation in the risk assessment and are intended to be protective of other groups exposed during the particular recycled water use.

- Child recreational exposure to PPCPs from dermal contact and incidental ingestion of recycled water while playing in parks and playgrounds irrigated with recycled water.

- Agricultural worker exposure to PPCPs from dermal contact and incidental ingestion of recycled water while working on fields irrigated with recycled water.
- Landscape worker exposure to PPCPs from dermal contact and incidental ingestion of recycled water while working in highway medians, street landscaping, or other areas irrigated with recycled water.
- Adult recreational exposure to PPCPs from dermal contact and incidental ingestion of recycled water while golfing on golf courses irrigated with recycled water.

Daily intakes for each PPCP were derived using concentrations detected in secondary and tertiary treated wastewater and assumptions regarding such variables as exposure duration, ingestion rates, skin absorption factors, and various other parameters that are used to describe human activities for the exposure scenarios. For some of the exposure factors, such as body weight and life span, the U.S. EPA provides default values intended to represent average exposures. These default exposure factors were used for many of the exposure parameters in this risk assessment. When default values were not available, conservative assumptions were used to derive exposure factors. The daily intake calculations used U.S. EPA intake equations.

Toxicity Assessment

A literature review was conducted to obtain toxicological information for the PPCPs included in the HHRA. The therapeutic doses, no observed adverse effect levels (NOAELs), and lowest observed adverse effect levels (LOAELs) for the selected PPCPs were identified from existing literature studies. The lowest therapeutic dose, NOAEL, and/or LOAEL for relevant toxicological endpoints for each PPCP was used in a hierarchy to select the toxicity value for use in the risk assessment.

Based on the toxicological information, acceptable daily intakes (ADIs) were identified for the PPCPs per the following peer reviewed hierarchy that was developed in WRF-05-005:

- 1) If the chemical is a pharmaceutical, select the lowest value from among comparison values derived using the following processes:
 - a. Divide the therapeutic dose (on a milligram per kilogram body weight basis, based upon the range of doses and age groups for which the chemical is prescribed) by a default uncertainty factor (UF) of 3000; divide by an additional UF of 10 if the compound is either a non-genotoxic carcinogen or an endocrine disrupting compound (EDC)
 - b. Divide the literature-based no observed adverse effect level (NOAEL) by a default UF of 1000 or the lowest observed adverse effect level (LOAEL) by a default UF of 3000; divide by an additional UF of 10 if the compound is either a non-genotoxic carcinogen or an EDC
 - c. If the compound is a genotoxic carcinogen and tumor incidence data are available, develop a slope factor and establish a comparison value assuming a *de minimis* cancer risk of 1 in 1,000,000.
 - d. If the compound is a genotoxic carcinogen and no tumor incidence data are available, use the lower of the virtually safe dose derived using the method of Gaylor and Gold (1998) or the threshold of toxicologic concern (TTC).

- 2) If the chemical is not a pharmaceutical and either a literature-based NOAEL or LOAEL can be identified or the chemical is a genotoxic carcinogen, set guidelines based on toxicological data following (b), (c), and (d), above.
- 3) If the chemical is not a pharmaceutical but does not have either a literature-based NOAEL or LOAEL or there is no evidence it is a genotoxic carcinogen, derive a comparison value based on the TTC.

Risk Characterization

Acceptable concentrations of PPCPs in recycled water were calculated for each of the non-potable use scenarios that were evaluated. The acceptable concentrations are based on the exposures calculated in the exposure assessment and the ADIs derived in the toxicity assessment. The acceptable concentrations represent the concentrations of PPCPs that can be present in recycled water and not exceed the ADI, based on the exposure scenarios evaluated in the risk assessment. The acceptable concentrations were calculated using the following general equation:

$$\text{Acceptable Concentration } (\mu\text{g/L}) = \frac{\text{ADI}(\mu\text{g/kg} - \text{day})}{\text{Exposure}(\text{L/kg} - \text{day})}$$

The acceptable concentrations were then compared with concentrations of PPCPs that have been measured in recycled water. If the measured concentrations are less than the acceptable concentrations, the PPCPs are not likely to result in adverse health effects for the exposure scenario. In all cases, the measured concentrations are less than the acceptable concentrations, indicating that actual exposures to non-potable recycled water will not result in adverse health effects.

To provide context for the concentrations of PPCPs detected in recycled water, the exposures that could result based on non-potable recycled water uses were compared with exposures that commonly occur for the PPCPs. Using the 90th percentile concentrations of PPCPs detected in recycled water (CSWRCB, 2010), the number of years of exposure to recycled water that would result in the same level of exposure that is common for PPCPs was calculated for each of the non-potable use scenarios. The study found that it takes between one and 190 million years of exposure to non-potable recycled water to get the same exposure to the PPCPs as a person might get from a single dose during common activities.

Conclusions

The results of the risk assessment indicate that measured concentrations of PPCPs in recycled water are less than the acceptable concentrations for non-potable uses of recycled water. Therefore, the presence of PPCPs in recycled water is not likely to result in adverse health effects for non-potable uses of recycled water. Furthermore, the results of the risk assessment indicate that risks from exposures to PPCPs resulting from non-potable uses of recycled water are many times less than risks from those same chemicals through common daily exposures to PPCPs.

These findings were incorporated into risk communication tools to support public review of recycled water projects. The key messages resulting from this report and used in the communication tools are as follows:

Recycled Water

- Recycled water is wastewater that has been treated to a level intended for beneficial reuse following the standards of regulators in the state in which it is being used. Tertiary-treated recycled water is considered safe for full human contact, but is not regulated for drinking. As water becomes a scarcer resource, many communities are making use of recycled water to address growing water demands and limited supplies.
- Communities that take advantage of recycled water must adhere to strict health and safety guidelines that require routine testing.
- Recycled water has safely been used to irrigate public facilities such as school grounds, athletic fields, golf courses, parks and common areas of residential neighborhoods for many years.

Pharmaceuticals and Personal Care Products (PPCPs)

- PPCPs are products used by individuals for personal health or cosmetic reasons. PPCPs comprise a diverse collection of thousands of chemical substances, including prescription and over-the-counter therapeutic drugs, veterinary drugs, fragrances, lotions, cosmetics and anti-bacterial soap.
- The treatment process for wastewater is not designed to remove all the chemicals that become part of the waste stream through human consumption and excretion. Numerous studies have shown that residual amounts of PPCPs remain in treated wastewater effluent at trace concentrations.
- We know the public is concerned about the presence of PPCPs in recycled water. But findings from the Risk Assessment study indicate it could take anywhere from a couple of years to many millions of years of non-potable exposure to recycled water to reach the level of exposure to the same compounds that we get in a single day through normal usage of some common products.
- The Risk Assessment Study determined that the presence of PPCPs in recycled water posed no significant health risks from non-potable uses. The concentrations of these chemicals in recycled water are extremely small and considered safe in typical usage situations.
- The presence of PPCPs has also been detected in drinking water and food products. The levels vary based on the type of food and the location of the drinking water source. Generally, the health risks from exposure to PPCPs through contact with recycled water are only a tiny fraction of health risks from normal exposure from food, medicines and personal care products.

Relative Risk

- Everything we do involves risk. Driving a car, riding in an airplane, swimming in the ocean, involve risk. The idea of being “safe” is a relative concept. As individuals we make decisions about our own safety and the relative risks we are willing to take. As a society, we make collective decisions about safety and risk. These decisions weigh the risks against the benefits. Understanding those risks and benefits is fundamental to making sensible choices.
- While scientists acknowledge that excess exposure to chemicals may pose health risks, many chemicals are in products that society views as beneficial. Therefore, “safe” or “acceptable” exposure levels are established for compounds that we come into contact with every day. This

study found that actual concentrations measured in recycled water are generally only a tiny fraction of acceptable concentrations for typical non-potable recycled water uses.

- In the study, a risk assessment was used to determine health risks by examining the toxicity of a chemical and the estimated exposure to that chemical under various scenarios. Risk is a combination of toxicity and exposure ($\text{Risk} = \text{Toxicity} \times \text{Exposure}$). The U.S. EPA's risk assessment methodology includes assessing exposure, dose and characterization of risk.
- "Relative exposure" can help us gain perspective on our concerns about health risks, and is determined by comparing the body's estimated intake of a chemical in different situations.

References

California State Water Resources Control Board (CSWRCB). Monitoring Strategies for Chemicals of Emerging Concern (CECs) in Recycled Water. Science Advisory Panel on Chemicals of Emerging Concern, Final Draft. 25 June 2010.

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