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	EXE	PERT REVIEW REPO	ORT	
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UNITED	STATES ENV	IRONMENTAL PRO	DTECTION AGEN	ICY'S
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APPL	ICATION TO S	SECONDARY CONT	TACT RECREATI	ON
Research and Dev	velopment Depa	rtment		
Louis Kollias, Ac				July 2006

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Ms. Rhonda Griffith is acknowledged for typing the foreword to this report.

DISCLAIMER

Mention of proprietary equipment and chemicals in this report does not constitute endorsement by the Metropolitan Water Reclamation District of Greater Chicago.

FOREWORD

The Illinois Environmental Protection Agency (IEPA) is currently conducting a Use Attainability Analysis (UAA) study on the Chicago Area Waterways (CAWs). <u>Appendix A</u> is a description of the CAWs. A Stakeholders Advisory Committee (SAC), which includes representatives of the United States Environmental Protection Agency (USEPA) Region 5, the U. S. Army Corps of Engineers-Chicago District, the Illinois Department of Public Health, the IEPA, the Illinois International Port Authority, the City of Chicago, the consulting firm of Camp, Dresser, and McKee (CDM) (the contractor for the IEPA), environmental advocacy organizations, representatives of navigation and industry, and the Metropolitan Water Reclamation District of Greater Chicago (District) was formed to guide the conduct of the UAA study. The IEPA has proposed two recreational use designations: 1) Limited Contact Recreation, which includes recreational boating (kayaking & canoeing), wading, and fishing; 2) Recreational Navigation, which includes non-contact activities such as pleasure boating and commercial boating for various portions of the CAWs.

One aspect of the UAA study is to determine whether the bacterial water quality standards for some or all parts of the CAWs are necessary to protect the proposed designated uses of the CAWs and, if so, to develop appropriate protective standards. In order to assist the IEPA in evaluating the need for, and development of bacterial water quality standards, the District commissioned qualified consultants (research scientists and water quality experts) to conduct a peer review of the USEPA's Water Quality Criteria for Bacteria – 1986 and November 2003 draft implementation guidance document. The report, entitled "Expert Review Report Regarding United States Environmental Protection Agency's Water Quality Criteria for Bacteria – 1986: Application to Secondary Contact Recreation," enclosed herein, was written by this expert review panel.

The USEPA criteria were formulated to protect public health. The USEPA's 2003 guidance for implementation of their ambient water quality criteria for bacteria is particularly important since the IEPA has relied heavily on this document in formulating proposed bacterial water quality standards for the CAWs in the UAA study. Because the CAWs are a unique urban river system and the USEPA's criteria and implementation guidance were developed mainly for beaches, the SAC recognized that it is important to verify and determine whether the scientific/technical information contained in the USEPA's 2003 guidance document is suitable for establishing sound bacterial water quality standards for the protection of human health relative to the proposed designated uses for the CAWs. This report is a critical evaluation of the science used by USEPA to develop ambient water quality criteria for bacteria (1986 Ambient Water Quality Criteria for Bacteria) as well as the USEPA's 2003 guidance document for the implementation of their 1986 criteria.

This report is very concise and highly technical in nature. For the benefit of readers who do not have detailed familiarity with the USEPA's 1986 ambient water quality criteria for bacteria, the original studies upon which they are based, the history of the USEPA's quest to implement them, or the use of indicator organisms to protect public health, the following information is provided to foster a better understanding of the findings in this report as well as their significance.

Addressed in the report are the historical scientific data which form the basis for current microbial standards for recreational freshwater. Prior to 1986, microbial water quality standards were based on total coliform (TC) and fecal coliform (FC) bacteria. As a result of the

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Cabelli (1983) and Dufour (1984) epidemiological studies, the USEPA (1986) recommended E. *coli* or enterococci spp. for monitoring the microbial quality of freshwaters. In 2000, the USEPA announced the intention "to promulgate federal water quality standards, with the goal of assuring that the USEPA recommended 1986 bacteria water quality criteria (1986 criteria) apply in all States, Territories, and authorized Tribes, as appropriate, by 2003." Numerous reports over the past two decades have been critical of the Cabelli (1983) and Dufour (1984) studies. In 2004, the USEPA used authority of the Beaches Environmental Assessment and Coastal Health Act of 2000 (BEACH Act) instead of the 1986 criteria to promulgate water quality standards based on E. coli for coastal recreation waters (69 FR 67217, November 16, 2004). The fact that a final implementation guidance for the water quality criteria published in 1986 is still not available suggests that there are still unanswered questions about the Cabelli and Dufour studies. The regulated and scientific communities continue to question the validity of the 1986 Ambient Water Quality Criteria for Bacteria (AMSA, 2004 and ASIWPCA, 2005) (Appendices B and C). (The Association of Metropolitan Sewerage Agencies [AMSA] & Association of State and Interstate Water Pollution Control Administrators [ASIWPCA] references cited were not "peer reviewed" for publication in a technical journal.) The cited and un-cited references in the body of this report can be consulted for more information regarding this controversy. Some of the major criticism is explained below.

The "USEPA Guidance Document" (USEPA, 2003) states that the new bacteria standards based on concentrations of enterococci spp. (EN) and *E. coli* (EC) indicator organisms are scientifically more defensible than the old standards, based on concentrations of TC and FC bacteria, because there are many environmental sources (e.g. soil, water, birds, sand, plants) for TC and FC; therefore, the concentrations of these two groups of fecal bacteria in environmental waters

often do not necessarily represent fecal contamination. However, EN and EC also have environmental sources (soil, plant, and water), so the same argument the USEPA used to reject TC and FC could be used to refute the usefulness of EN and EC as indicators. These extraneous sources of indicator organisms best explain why environmental beaches routinely exceed USEPA-recommended recreational water quality standards. In general, the position of the regulated community and some experts in the scientific community is that the 1986 criteria replaced an imperfect indicator with two other imperfect indicators, and that more studies are required.

From the epidemiological studies (study of disease in populations) conducted in the 1970s and early 1980s, it was inferred that there exists an approximate trend for human pathogens to be at higher levels whenever indicators are at higher levels. This hypothesis and the ideal microbial indicator criteria concept has not been widely tested, evaluated, or validated. The World Health Organization (WHO) and some of the USEPA experts have acknowledged a number of constraints in the current standards and guidelines for recreational water in a document entitled, "Health-Based Monitoring of Recreational Waters: The Feasibility of a New Approach (The Annapolis Protocol)." This WHO (1999) report is attached in <u>Appendix D</u>, which succinctly states the following:

Present regulatory schemes for the microbiological quality of recreational water are primarily or exclusively based on percentage compliance with fecal indicator counts. A number of constraints are evident in the current standards and guidelines:

- management actions are retrospective and can only be deployed after human exposure to the hazard (because of the time required to conduct microbial indicator analysis);
- the risk to health is primarily from human excreta, the traditional indicators of which may also derive from other sources;
- there is poor inter-laboratory and international comparability microbiological analytical data.

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Based on this document, there is good evidence that public health is not protected by the use of common fecal indicators. The USEPA has not adequately addressed the scientifically valid criticisms of the Cabelli and Dufour studies. The failure on the USEPA's part to issue the final implementation guidance reflects the controversy and criticism associated with the original USEPA studies used as a basis for the 1986 criteria.

There are some fundamental reasons why the USEPA cannot develop guidance for implementation of the 1986 criteria, which will be universally applicable to the waters of the United States. The Cabelli and Dufour studies which are the basis for the 1986 criteria are epidemiological studies that statistically correlate indicator organism concentrations and incidence of illness in swimmers exposed to the water, formulating a relationship between indicator organism concentrations and health effects. In these studies, no attempt was made to evaluate the actual level of exposure (i.e., length of time in the water, extent of contact with the water, amount of water ingested, etc.) of each swimmer at the beaches studied, nor was any attempt made to evaluate the relationship between levels of indicators and actual pathogenic organisms at the study sites. Because of this, it is not possible to accurately and reliably apply the results of these studies in developing criteria for secondary contact recreation that occurs along the CAWs, since the level of exposure and relationship between indicator organisms and actual pathogens is likely very different at the CAWs than at the beaches used in the Cabelli and Dufour study.

The format of the expert review report is structured around seven tasks, A through H. Each task is followed by its own specific list of findings, conclusions, and recommendations. Based on the data that were reviewed, the expert review panel compiled a list of 20 findings and 12 recommendations regarding the 1986 criteria, the 2003 guidance document, and the USEPA studies. The most important findings relative to the UAA study being conducted on the CAWs are listed below

- □ The USEPA confirms that there are virtually no scientific data available on which to rationally base national criteria for secondary contact recreational exposure.
- □ None of the underlying epidemiological studies upon which the 1986 USEPA ambient water quality criteria for bacteria are based directly addressed the issues of secondary contact.
- □ The USEPA (statistical) model is not applicable to the CAWs and cannot be used to produce secondary contact water quality standards.
- □ There is no direct USEPA guidance regarding the application of the 1986 ambient water quality criteria for bacteria to the proposed recreational uses of the CAWs, which are secondary contact.
- □ A formal microbial risk assessment or epidemiological study needs to be conducted to ascertain risk from secondary contact activities in CAWs. The relationship between multiple exposure risks (gastrointestinal disease; skin, respiratory, eye, or ear infections) to microbial indicator and pathogen concentrations is required to develop acceptable health risk guidance.
- □ The IEPA should develop a detailed methodology for a secondary contact standard, following USEPA recommendations, to be used in a CAWs UAA study. The standard should be based on additional information (water quality monitoring, exposure, and health effect data) as outlined above.
- The CAWs' UAA study approach has not made an explicit and detailed characterization of a secondary contact level of exposure and appears to rely mainly on using five times (5x) the primary contact guidelines. This approach lacks proper scientific foundation and needs further investigation to derive a more appropriate jurisdictional limit as recommended by USEPA's 2003 guidance. Therefore, the USEPA recommendation that each jurisdiction evaluates an appropriate secondary contact criterion has not been enacted in Illinois.
- □ There is a contradiction between the USEPA 2003 guidance document and the UAA study on the issue of designation of kayaking activity for some portions of the CAWs. The UAA SAC included kayaking as a limited contact recreational activity, while the USEPA defines kayaking as a primary contact activity. Until this issue is resolved, kayaking activity in the CAWs needs to be prohibited by the use of warning signage postings.

In summary, it is clear from findings of the expert review panel and the reviews/criticism of others that the epidemiological studies relied on by the USEPA to promote the primary contact swimming activity (immersion) microbial criteria were not designed to generate secondary contact recreational standards. Consequently, the data derived from these studies are "unsuitable for the development of a national secondary contact criterion." This fact is acknowledged by USEPA in their 2003 Guidance Document (pages 40-41).

The findings of the expert review panel indicate that at this time there is no scientific basis for developing bacterial water quality standards for the CAWs. The District encourages the IEPA to seriously consider the recommendations of the expert renew panel, contained in this report, to remedy this situation.

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Expert Review Report Regarding United States Environmental Protection Agency's Water Quality Criteria for Bacteria -- 1986: Application to Secondary Contact Recreation

Prepared for the Metropolitan Water Reclamation District of Greater Chicago

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A. Introduction

The Illinois Environmental Protection Agency (IEPA) is conducting a Use Attainability Analysis (UAA) of the Chicago Area Waterways (CAWs), primarily focused on the Chicago and the Calumet River Systems. With the exception of three CAWs reaches, the CAWs are currently designated as Secondary Contact and Indigenous Aquatic Life and have no bacterial water quality standards. The IEPA is conducting this UAA to determine whether a use upgrade for balanced aquatic life and contact recreation are achievable and to determine whether relatively recent upgrades of General Use reaches in the CAWs were appropriate. Once the IEPA designates a use or uses for all reaches of the CAWs then water quality criteria need to be developed to protect those uses.

The use designation that is being proposed for most of the CAWS is Limited Contact Recreation which is described as:

"These waters shall protect for incidental or accidental body contact during which the probability of ingesting appreciable quantities of water is minimal including: recreational boating (kayaking, canoeing, jet skiing) and any limited contact incident to shoreline activity, such as wading and fishing. Protection requires the attainment of 30-day geometric mean 1030 cfu *E. coli* standard based on 10 illnesses per thousand contacts."

The use designation that is being proposed for the CAWs downstream of the Stickney WRP is Recreational Navigation, which is described as:

"These waters shall protect for non-contact activities including, but not limited to pleasure boating and commercial boat traffic operations. Protection would require attainment of a 30-day geometric mean 2740 cfu *E. coli* standard is based on 14 illnesses per thousand contacts."

These use designations are proposed to replace the current Secondary Contact use designation which has no bacterial water quality standard associated with it. It is presumed that the bacterial water quality standards associated with these new use designations are based on the United States Environmental Protection Agency's (USEPA) 1986 Ambient Water Quality Criteria for Bacteria document and a November 2003 draft Implementation Guidance for Ambient Water Quality Criteria for Bacteria.

A reclassification of CAWs to a designation requiring compliance with a stricter level (lower concentration) of microbial indicator organisms to achieve lower exposure to recreational users would require additional investments on the part of the District that need to be balanced with defined benefits to public health and the environment. Therefore, MWRDGC has commissioned this panel to systematically review aspects of the 1986 and 2003 documents, and related information, and conduct the following tasks:

- Evaluate USEPA's 1986 Criteria for Primary Contact Waters
- Evaluate suitability/applicability of scientific data upon which USEPA's 1986 Criteria are based (i.e., Cabelli study (1983) & Cabelli *et al.* study (1982)). This evaluation should address the scientific data or the evidence linking specific microbial indicators of recreational water quality to specific health outcomes for the CAWs.
- Evaluate sufficiency of scientific data upon which USEPA's 1986 Criteria are based (i.e., Cabelli study & Cabelli *et al.* study) and evaluate prevalence of data and information that are currently available.
- Evaluate suitability of statistical models and methodology utilized to formulate USEPA's 2003 guidance and their applicability to the CAWs.

- Evaluate the conclusions that USEPA drew from the available data in the 2003 guidance and their applicability to the CAWs.
- Evaluate the extent to which USEPA's 2003 guidance is applicable to likely exposure scenarios for the CAWs
- Evaluate use of USEPA's 2003 guidance in the CAWs UAA study

In performing these tasks, the panel met with District personnel in July and December 2005, reviewed pertinent literature and reports, and also physically toured substantial portions of the CAWs. Our conclusions in this document report on the consensus of the panel regarding the specific questions.

As background to this task, it is recognized (and has long been understood) that the 1986 and 2003 documents (and their predecessors) that rely on indicator organisms for the assessment of public health risk are an indirect approach. In general, indicator organisms (coliforms, enterococci) do not in and of themselves cause human illness¹. However, in developing the guidance and criteria, which rely upon epidemiologic studies (study of disease in populations) conducted in the 1970's and early 1980's, it was implicitly recognized that there exists an approximate trend for human pathogens to be at higher levels whenever indicators are at higher levels. This hypothesis has not been widely tested.

Since 1986, in a wide variety of contexts, USEPA has moved towards guidance and standardsetting approaches based on direct risk assessments of contaminants of health significance. Over the same time frame, the methodology of quantitative microbial risk assessment (QMRA) (Haas *et al.*, 1999) has been extensively developed. The USEPA 1986 criteria are not risk based but rather are based on a small set of site specific epidemiological studies that were conducted at bathing beaches. To date USEPA has not developed a risk based approach to setting criteria for microbiological water quality standards in recreational waters. It should be possible to develop an alternative framework for setting recreational water criteria using such approaches – however this development was beyond the charge of this panel. Reliance on epidemiologically derived information assumes similarity of use and exposure scenarios, and water quality and environmental conditions.

Finally, it is recognized that the results of any re-evaluation of appropriate receiving water criteria for CAWs may necessitate substantial modifications in treatment at one or more of the facilities of the MWRDGC. This panel takes no position on such modifications – a task that is beyond our charge.

B. Evaluate USEPA's 1986 criteria for primary contact waters.

Water recreation may mean different things to different groups and include a wide array of activities. Primary contact refers to direct full-body contact and often is used to mean swimming, surfing, scuba diving and even activities where one may often fall in the water such as water skiing, wind surfing and kayaking. Three potential routes of exposure have been identified with direct contact, the first and one of greatest exposures is accidental ingestion of the water. Estimates have been made of anywhere from 50 to 100 ml of water ingested per

¹ The expert panel recognizes that certain strains of these organisms are human pathogens, however the use of indicators is not based on the presence of these pathogenic strains, but the assumption that there is a relationship between the indicators and pathogens.

swimming event: in fresh water greater ingestion occurs then in salt water. There is also exposure to parts of the body, including the ears, eyes, mouth and throat, and inhalation of water. Exposure is a key component of the risk, the greater the exposure to a contaminated water body the greater the risk, this could be seen via the type of activity and the frequency at which that activity was undertaken. In a number of studies young children were identified as having the greatest exposure (Alexander, et al. 1992). It should be noted that secondary exposure may include activities such as walking in the water, playing in the water or sand, boating and fishing where direct contact of the water with the body, primarily the hands does occur, inhalation could also occur via waves, wind and splashing. Indirect contact such as handling paddles, canoes and fish would also occur. It is not clear how much exposure (eg. in mililiters) would actually take place with each individual activity under the umbrella of "secondary contact". It is critical to identify and characterize these differences in exposure that occur due to primary and secondary contact if relevance of epidemiologically based criteria that were developed at primary contact sites are to be evaluated for applicability to secondary contact sites.

In the late 1940s and early 1950s, swimming and health studies were conducted at a Lake Michigan beach, in Chicago IL, as well as on the Ohio River at Dayton KY. These were some of the first recreational epidemiological studies undertaken. Stevenson (1953) was one of the first to report on the relationship between disease and recreational exposure to waters containing various levels of fecal indicator bacteria. In this study, total coliform bacteria above 800 CFU/100ml were associated with gastrointestinal disease. Swimming was the main exposure in these studies. Interestingly, this study used individuals in the same households (not individuals at the beach who possibly had some exposure but not primary contact to the water) who were non-swimmers as controls and the non-exposed population. Some increase in skin infection, but primarily gastroenteritis was noted as the health effects that distinguished the swimmers from the non-swimmers. The definition of the gastroenteritis could not be obtained from the published paper.

By the 1970s after USEPA was first formed, illness-associated with recreating in water impacted by non-disinfected sewage was under discussion. At that time, several more epidemiological studies were undertaken, to evaluate the impact of water quality on health of swimmers recreating in these waters (e.g., Cabelli *et al.*, 1982). Exposure (swimming) was defined as immersion of the head under water. The definition of health impacts in these studies was quite stringent and was termed "highly credible G.I." which included any of the following: 1. vomiting; 2. diarrhea with fever; or 3. Stomachache or nausea with a fever. Thus diarrhea without a fever was not considered, nor was nausea, respiratory illness, skin infections, nasal infections or eye infections. It is likely that illnesses due to some viruses and protozoa such as *Cryptosporidium* and *Giardia* would not have been identified in these studies.

We note that the definition of exposure in these studies (immersion of the head under water) does not directly assess exposure. Specifically, the volume of water ingested (which with concentration of a pathogen or perhaps an indicator would comprise the dose) was not directly assessed. Furthermore, it was presumed that all individuals were equivalently susceptible, and correction for other possible confounders or modifying factors -- such as health status, nutrition, or other routes of exposure to infectious agents --, was not undertaken.

In the USEPA studies reported by Cabelli and Cabelli *et al. (1982)*, beaches at lakes were investigated and increasing enterococci concentrations were shown to provide the best statistical fit to increasing illness rates in the fresh waters, although *E. coli* also had a statistically

significant association to illness. It was suggested that this was due to the superior ability of the enterococci bacteria compared to fecal coliforms and *E. coli* to survive in the environment and resist disinfection.

In the USEPA studies reported by Cabelli and Cabelli *et al. (1982)*, highly credible illness was found to range from 1.3% to as high as 2.5% in the swimmers in these studies at several freshwater beaches. Only at one of the beaches was total gastrointestinal illness examined rather than highly credible illness (HCGI) which was the more stringent measure of more severe illness mentioned above. HCGI included nausea, vomiting, diarrhea or stomachache. Illness rates(HCGI) ranged from 2.9% to 9.5% in the swimmers and in the non-swimmers illness rates ranged from 0.9% to 8.7%. Interestingly, after plotting the data reported for the swimmers and non-swimmers illness rates, the rates had a 0.67 correlation (Figure 1) (un-weighted for sample size). One cannot readily interpret these data, as the study was not set up to address non-swimming exposures. However, this association supports a hypothesis (which would need further testing) that perhaps those on the beach who did not swim, but were ill, were influenced to a lesser extent by the water quality via activities such as playing in water or the sand with minimal exposure (secondary exposures including indirect exposure via hands and skin and perhaps inhalation of aerosols).

The 1986 recommendations for the *E. coli* and enterococci criteria emerge from the USEPA document on the "Bacteriological Ambient Water Quality Criteria for Marine and Fresh Recreational Waters", (US EPA, 1986). Table 1 shows the USEPA criteria.

	Geometric	Single Sample
	Mean ^a	Maximum
Marine Water		
enterococci	35	104
Fresh Water		
enterococci	33	61
E. coli	126	235

Table 1. 1986 Surface water quality criteria (CFU/100mL) proposed by USEPA for primary contact recreational use (US EPA, 1986).

^a Based on not less than 5 samples equally spaced over a 30-day period.

From 1973 to 1982, 10 beaches were studied; four of these were fresh water beaches in Lake Erie. The same beaches from 1979 to 1982 were investigated two or three times, resulting in essentially 9 epidemiological trials (tests). Illness rates at the fresh waters ranged from 1.1% to 2.6% and were lower than the marine beaches (0.8 to 4.6%). However, in the freshwater, only two of the 9 trials showed statistically significant difference in illness rates between the swimmers and non-swimmers. In Figure 1, only the two points at the right (enclosed within the ellipse) were ones in which there was a statistically significant difference between control and swimmer populations, and both of these points were located at Lake Erie. However there was a strong general trend for risk to swimmers at all venues to be greater than risk to nonswimmers.

Since secondary contact was not a focus of concern when these studies were conducted, there was no discussion of "secondary contact criteria" in this document. Thus the freshwater data have greater limitations statistically in determining appropriate criteria for water quality. Disease transmission via contact, which could have informed the secondary contact issues, was simply not considered.

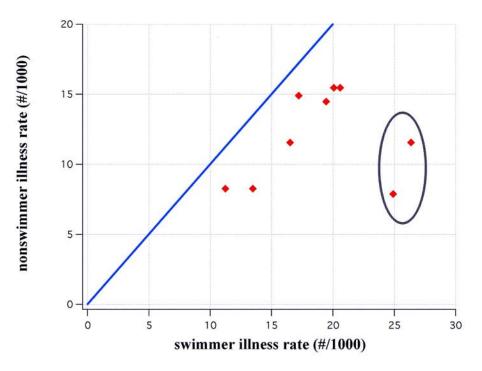


Figure 1. Illness rates in swimmers and non-swimmers in the nine freshwater data sets used by USEPA (1986). The two points located within the ellipse were those where there was a statistically significant difference between illness rates in control population

There are other limitations to the epidemiological database used, which are discussed further in section B below. Given the database which was used by USEPA, the limit of sensitivity was approximately a swimmer illness rate of 8 per 1000 in freshwater (corresponding to that which was found when the subject beaches were in compliance with the then existing 200 fecal coliform/100 mL criterion) and thus this was regarded as acceptable. The regression results for illness versus either *E. coli* or enterococci were used to develop criteria for geometric mean levels of these indicators corresponding to the target acceptable risk level.

To get maximum acceptable levels (termed "exceedance" levels) (e.g., 95%, single sample maximum, etc.), USEPA then applied the observed log-standard deviations from the studies to estimate statistical confidence limits. USEPA noted specifically (1986 document, page 15) "During the USEPA studies [the log standard deviation was]: 0.4 for freshwater *E. coli* and enterococci...Each jurisdiction should establish its own standard deviation for its conditions which would then vary the single standard limit." It is observed that, to the knowledge of the panel, few jurisdictions have appeared to determine locality specific standard deviations as suggested by USEPA. It would be expected that this level of variability is influenced not only by the nature of discharges to the watershed, but by hydrologic and climatologic factors, which would clearly be site specific.

Findings and Conclusions

F1. In the USEPA studies, the strength of association between swimming and illness in the freshwater sites was weak – only two of 9 trials showed a statistically significant difference between swimmers and controls. This may be reflective of the insufficient

power of the studies (too few subjects), or high levels of illness in the nonswimming control individuals in the studies.

- F2. The determination of enterococci and *E. coli* criteria for primary contact waters given the epidemiologic information determined was appropriate, although (as noted in section D) alternative approaches leading to higher criteria values are also consistent with the data.
- F3. USEPA's determination of the single sample maximum for primary contact is based upon an assumed log standard deviation for the indicator (enterococci or *E. coli*) to be used. USEPA has recommended that the log standard deviation be determined by each jurisdiction, which has rarely occurred.

Recommendations

R1. To employ the USEPA approach with respect to single sample maxima, site-specific (or at a minimum waterway specific) log-standard deviations for indicators (enterococci and *E. coli*) should be determined in accordance with USEPA's recommendation (1986 *Ambient Water Quality Criteria for Bacteria*, page 15). This should be based on a well-designed sampling plan encompassing the variability in weather and hydrology encountered.

C. Evaluate sufficiency of scientific data upon which USEPA's 2003 Criteria are based (i.e., Cabelli study & DuFour study) and evaluate prevalence of data and information that are currently available.

The studies and statistical analyses that the USEPA used have been criticized (Fleisher, 1991). He found that the analysis was flawed and the criteria developed not useful for predicting illness due to the geographic differences particularly in regard to the different salinities (Lake Pontchartrain, a brackish water body, was included within the marine studies). Pruss (1998) also undertook a review and found that the relationships between indicator organisms and disease from one epidemiological study to another (at different geographical sites and different time periods) were highly variable. However, in a more rigorous meta analysis with many more studies by Colford for the National Academy of Sciences (Wade *et al.* 2003), it was found that enterococci levels did provide the best statistical relationship to health impacts from swimming activities (considering USEPA and other studies). They also considered the issue of safety, that is they found no evidence that there was a health risk when the criteria were met. Several other issues emerged.

- 1. There were fewer studies in freshwaters than in marine waters, thus while statistically significant, there was less scientific evidence used to build the relationships.
- 2. The geometric mean and single sample criteria chosen provided a level of safety or threshold (that is no excess illness was observed under those conditions in swimmers). But it was difficult based on the data to say what the confidence range around those numbers was.
- 3. *E. coli* levels were also found to provide an adequate relationship to the health of swimmers in freshwaters. This is shown by the results of the meta-analysis conducted by Wade *et al.* (Figure 2).
- 4. Coliphage viruses and enteric viruses also were found to show some statistical relationships (however very few trials examined the viruses).

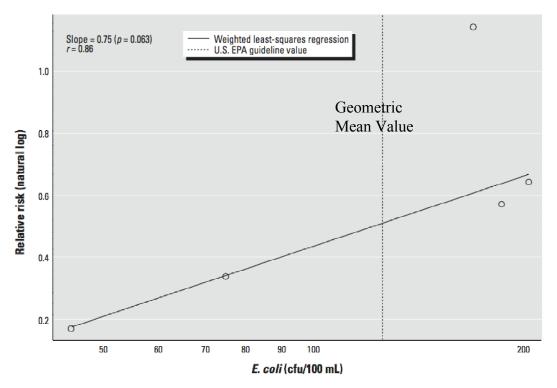


Figure 2. Weighted regression meta-analysis of relative risk of GI illness in freshwater from primary exposure (Wade *et al.* 2003).

In the context of the current problem at hand – exposure to individuals during secondary contact activities such as boating, the data underlying the 1986 criteria are not informative, since the studies were not designed to elicit the risk associated with such activities.

In fact, even to the present time, there have been very few studies conducted to examine risks associated with secondary contact recreational activities. The only study on secondary contact exposure that this review panel is aware of was reported by Fewtrell et al. (1994). In this study of the risk to individuals engaged in canoeing and rowing in several English rivers, it was found that the health effects were undetectable (with respect to gastroenteritis) even in waters with fecal coliforms as high as 4613 organisms/100 mL, providing that individuals did not fall (e.g., did not capsize) into the water. In the approximately 10% of such individuals who did fall in the water, there were statistically discernable adverse health effects, such as skin but also gastroenteritis infections.

There is a further limitation in that the underlying data (from the USEPA studies) on freshwater exposures is quite limited (e.g., Lake Erie) and only involves exposure in lake settings (at designated beaches) rather than in settings bearing similarity to the CAWs.

USEPA has recognized the absence of evidence to quantitatively derive riskbased standards for secondary contact (see the accompanying box). A default ratio of 5 times the primary contact standard for fecal coliform (and implicitly for alternative indicator organisms) has been suggested as an approach. However, it is not clear what justification states used to formulate this number.

<u>Findings and</u> <u>Conclusions</u>

F4. While there are additional data in the form of epidemiological studies of primary contact exposure to freshwater, beyond

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Many states and authorized tribes have adopted secondary contact recreation uses for waterbodies. States and authorized tribes with fecal coliform criteria generally have adopted a secondary contact water quality criterion of 1000 cfu/100ml geometric mean, which is five times the geometric mean value typically used to protect primary contact recreation. This water quality criterion has been applied to secondary contact uses and to seasonal recreation uses during the months of the year not associated with primary recreation. The *Ambient Water Quality Criteria for Bacteria* –1986, which recommended *E. coli* and enterococci as indicators, did not provide criteria recommendations for recreation uses other than primary contact recreation. States and authorized tribes have cited this as one reason why they have not adopted EPA's recommended water quality criteria.

EPA is unable to derive a national criterion for secondary contact recreation based upon existing data, because secondary contact activities involve far less contact with water than primary contact activities. During the development of this guidance document, EPA explored the feasibility of deriving criteria for secondary contact waters and found it infeasible for several reasons. In reviewing the data generated in the epidemiological studies conducted by EPA that formed the basis for its 1986 criteria recommendations, EPA found that the data would be unsuitable for the development of a secondary contact criterion. The data collected were associated with swimming- related activities involving immersion. Secondary contact recreation activities generally do not involve immersion in the water, unless it is incidental (e.g., slipping and falling into the water or water being inadvertently splashed in the face).

the Cabelli and Dufour data used by USEPA, it is not clear that these would substantively alter the nature of the conclusions developed by USEPA in 2003.

- F5. There remains a dearth of data on the quantitative relationships between microbial water quality and risk of illness from primary contact recreation in freshwater, however what data are available support the use of *E. coli*, and to some degree enterococci in this application.
- F6. There are virtually no data available on which to rationally base criteria for secondary contact recreational exposure, either in freshwater or marine situations.
- F7. In one limited study, individuals who did not fall into the water during boating (Fewtrell *et al., 1994*) reported no adverse health effects when geometric mean fecal coliform levels were below 4613 organisms per 100 mL.

Recommendations

- R2. Studies to ascertain risk from secondary contact in freshwater, and the relationship between any such risk and indicator levels need to be conducted. These may be epidemiological studies designed with sufficient statistical power to detect risks at the levels deemed to be acceptable for regulatory purposes. Alternatively, a formal microbial risk assessment can be conducted and more water quality monitoring for a variety of indicators and pathogens is appropriate.
- R3. A survey of other states and jurisdictions with respect to the rationale for their adoption of secondary contact guideline should be conducted.

D. Evaluate suitability/applicability of scientific data upon which USEPA's 2003 Criteria are based (i.e., Cabelli study & DuFour study). This evaluation should address the scientific data or the evidence linking specific microbial indicators of recreational water quality to specific health outcomes for the CAWs.

The freshwater *E. coli* and enterococci criteria (for primary recreational water) were based on nine separate data sets – each an epidemiologic study at a particular beach during a particular occasion. However, there were only two locales represented at these beaches – a Lake Erie set of beaches in Ohio and Keystone Lake in Tulsa Oklahoma. Both of these sites are large lakes. It is therefore an open question as to any similarities and differences between these sites and river recreational areas (such as in CAWs). These differences include factors such as sedimentation of particulates (expected to be greater in lakes), resuspension (expected to be greater in rivers), potential for bathers to be a principal source of contamination (expected to be greater in lakes) and significance of urban and agricultural runoff.

In none of the USEPA studies noted above was a control group used that did not visit the beach. One could hypothesize thus that the non-swimmers were not truly "unexposed" since some may have engaged in such non-swimming activities as wading, fishing and playing in the sand (such misclassification would have biased the estimated risk of the exposure downwards). Furthermore, there may be unknown confounding factors (age, health status, other risk behaviors, etc.) between a decision on the part of an individual to swim or not to swim, and the susceptibility to any exposure.

For the non-swimmers there was no discussion in the USEPA criteria (US EPA, 1986) or guidance (USEPA 2003) of the type of exposure to the water or wet sand. Thus one can imagine a number of types of exposures, including boating, walking in the water, playing in the wet sand with the hands, and potentially aerosol exposure (due to wind and wave action). It does appear that if increasing illness was related to water quality in the swimmers then there is also some secondary relationship to illness for those non-swimmers (Figure 1), yet much more tenuous and variable, which might make sense given the variation in exposures mentioned above.

The focus of the epidemiological studies employed by USEPA in the development of criteria (and basically all such studies available) has been on gastrointestinal illness. Hence these studies are of little value with respect to ascertaining the risk from skin, respiratory, eye or ear infections arising from non-swimming activities.

Findings and Conclusions

- F8. The freshwater data used by USEPA in establishing freshwater primary contact recreational guidelines were confined to only two lake locations, and their widespread applicability, to rivers in urban locations has not been ascertained.
- F9. None of the underlying epidemiological studies done to support the USEPA guidelines directly addressed the issues of secondary contact.
- F10. None of the underlying epidemiological studies done to support the USEPA guidelines directly addressed the issues of illness via skin, respiratory, eye or ear routes.

Recommendations

- R4. Studies to develop criteria for secondary contact, including specifically urban rivers should be conducted. These studies should address multiple exposure pathways.
- R5. Since no information is available in the Cabelli and DuFour data on which to assess the potential or absence of skin, respiratory, eye or ear infection risks resulting from secondary contact, and so if these are deemed of concern for secondary contact, additional studies should be performed to assess their significance.

E. Evaluate suitability of statistical models and methodology utilized to formulate USEPA's 2003 guidance and their applicability to the CAWs.

This section focuses upon the models used by USEPA to develop guidance, rather than upon the databases used for that process.

The data set USEPA used to derive the freshwater guidelines is given in Table 3 in the USEPA document (Ambient Water Quality Criteria for Bacteria-1986). USEPA's criteria (Table 1) are based on a simple linear regression model (equation 1) in which the difference between illness rates of swimmers and non-swimmers is used as the response variable and log_{10} (mean) bacterial indicator is used as the explanatory variable.

incremental $risk = a + b \cdot \log_{10}(indicator \ concentration)$ (1)

The number of data points (in the freshwater epidemiologic data set used by USEPA) is not sufficient to assess the adequacy of the model and to make inferences about the indicator level that corresponds to a given illness rate particularly for the freshwater beaches. It can be seen in Figure 3 below, that there is a great deal of scatter and a suggestion of nonlinearity in response. This suggests the inadequacy of the assumption of linearity. Even if the linearity assumption is accepted the estimation method (based on least squares) is not the most efficient (in a statistical sense) but more importantly the conclusions derived from the regression analysis are not accurate due to the inaccuracy of the estimated standard errors. This is due to two reasons:

- 1. The response variable is a difference of two rates (swimmers–nonswimmers) and thus a regression model based on the binomial distribution (logistic), which is applicable to proportions, is more appropriate.
- 2. The numbers of swimmers and non-swimmers have not been considered in model fitting and inferences. These should have been used as weights in model fitting, derivation of parameters, and estimating standard errors.

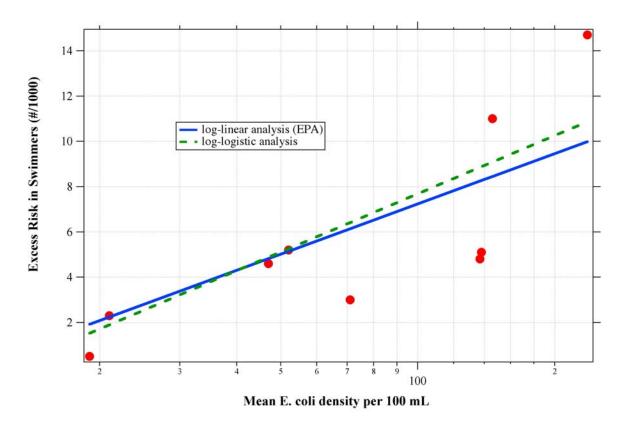


Figure 3. Relationship between mean *E. coli* concentration and illness rate for swimmers.

In the figure, the fitted model shown with the broken line gives the logistic regression model while the solid line gives the least squares fitted model. The slope based on the logistic model is higher and more significant. Table 2 gives the estimates of regression parameters and their standard errors as well as the estimated indicator level for 8 illnesses per 1000 swimmers.

Another problem with the model is the grouping of the data per swimming season (at each beach). The internal variation within season should have been incorporated in the analysis. Note

1 4010 2.	ble 2. Summary of Log-Linear and Log-Logistic Regressions for Excess Risk.			
Model	Intercept (std error)	Slope (std error)	Criterion (#/100 mL of <i>E. coli</i> corresponding to an excess risk in swimmers of 8 per 1000)	
Linear	-7.509 (5.432)	7.372* (2.875)	126	
Logistic	-9.409* (0.435)	8.546* (0.226)	109	

Table 2. Summary of Log-Linear and Log-Logistic Regressions for Excess Risk.

that the two extreme points are found in beach B in 1980 and 1982 (the points with excess risk >10/1000 in Figure 3). The ignoring of the within season variability may be the reason for the occurrence of the consistent positive difference between the illness rates for swimmers and non-swimmers.

Findings and Conclusions

- F11. The USEPA model is not applicable to CAWs and can't be used to produce secondary contact water quality guidelines. A study design is needed to extend the scope of the USEPA model beyond its limited range of application.
- F12. The use of un-weighted log-linear regression to fit the epidemiological studies was not the most appropriate statistical model. The log-logistic model produces better fit, and additionally there is a possible nonlinearity in response, which is difficult to test with the small number of data points.
- F13. In the USEPA analysis, the grouping of all data by swimming season ignores the intraseason variability at a given site².
- F14. If an adequate epidemiological database pertaining to secondary contact were amassed, then a weighted log-logistic analysis would be appropriate for its analysis.

Recommendations

- R6. Further research is required to develop an appropriate model for analysis of epidemiological data for the purpose of developing guidelines for the CAWs.
- R7. Since the USEPA model has serious limitations as the base for setting the guidelines for primary water contact, more appropriate systematic reanalysis of USEPA and other epidemiological studies to derive criteria using best available statistical models should be undertaken. This should, if possible, not be based on grouping data per swimming season (as USEPA has done), but rather by considering the best estimate of exposure for each individual exposed (and each control individual).

F. Evaluate the conclusions that USEPA drew from the available data in the 2003 guidance and their applicability to the CAWs.

With the passage of the BEACH Act (Beaches Environmental Assessment and Coastal Health (BEACH) Act of 2000) there has been a new look at the criteria and approaches used to address recreational waters. The BEACH Act is focused on coastal beaches (mostly marine), however, the Great Lakes beaches are considered to be a part of this and have been included.

Several interesting points have been made in regard to USEPA's positions on recreational waters in the Draft on *Implementation Guidance for Ambient Water Quality Criteria for Bacteria*

- 1. It is acknowledged that animal fecal inputs and impairment of waters due to animals may be a health risk due to pathogens such as *Campylobacter, E. coli* 0157H7, *Salmonella, Cryptosporidium* and *Giardia*, which can originate from animals as well as humans and cause human illness.
- 2. Kayaking is considered primary contact recreation by USEPA but is considered by Illinois EPA as a secondary contact activity in their UAA study report (www.chicagoareawaterways.org/index.php/Documents/CAWS UAA DRAFT REPORT).
- 3. The data used to develop primary recreational water quality criteria could not be used to develop secondary recreational water quality criteria.
- 4. Some states had used the 5x the numbers generated for primary contact, however this was not endorsed by the USEPA.

² Prior personal communication between CN Haas and Al Dufour suggests, unfortunately, that the raw data to perform an ungrouped analysis is no longer available.

The overarching observation of USEPA that is most relevant to the CAWs situation is the note that "States and authorized tribes with fecal coliform criteria generally have adopted a secondary contact water quality criterion of 1000 cfu/100 mL geometric mean, which is five times the geometric mean value typically used to protect primary contact recreation." However this observation was presented by USEPA without referencing which states have adopted this (or alternative values), or without justification for there in fact being any identified health impact. There is no supporting data presented by USEPA to demonstrate that there is a scientific basis for this approach and to enable scientific scrutiny of its basis and effectiveness.

Findings and Conclusions

- F15. The observation by USEPA of prior uses of a secondary contact guidelines of 5x the primary contact guideline is the only federal information to inform water quality criteria in the CAWs, however as noted above, USEPA did not explicitly endorse this but merely mentioned that such approaches have been used by states. This approach needs further investigation to derive a more appropriate jurisdictional limit as recommended by USEPA in its 2003 document.
- F16. Kayaking should be regarded as primary contact with water quality requirements identical to primary contact (swimming) and should not be considered for the CAWs.

Recommendations

R8. To the degree to which kayaking occurs in the CAWs (and during the field visit of the team, we did observe this), the postings should more explicitly warn against this activity, until such time as it is determined, either via risk assessment or epidemiological study specific to the CAWs that the risk to kayakers is acceptable.

G. Evaluate the extent to which USEPA's 2003 guidance is applicable to likely exposure scenarios for the CAWs.

All areas of the CAWs are classified for secondary contact and indigenous aquatic life, and are suitable for activities that would result in secondary contact. Both the North Shore Canal and the North Branch of the Chicago River are physically suitable for canoeing and kayaking. The expert team during its survey of the CAWs observed a number of types of recreational activity, and interviews with waterway users confirmed other types of uses. Parks and bridges provide locations for fishing and for walking and jogging. Riverside restaurants, some with outside seating, have been developed on the banks of the Chicago River. Further development of the area is possible. On the South Branch of the Chicago River there are parks and access for boating and fishing. Boating and related water activities take place in Chicago Sanitary and Ship Canal, the Chicago River, Little Calumet River, and the Calumet-Sag Channel. In the further south areas the waterways are sufficiently large that power boating and water-skiing are likely to occur.

Different uses of a recreational water would result in different sources and magnitudes of exposure. Primary contact uses, such as swimming, would result in ingestion, as well as dermal, and eye, ear, nose and skin exposure. Secondary contact exposure would typically only result in (at most) dermal and eye, ear, nose and skin exposure depending upon the type of activity (for example shoreline fishing likely resulting in lower exposure than canoeing).

The data that are presented and analyzed in the draft Implementation Guidance for Ambient Water Quality Criteria for Bacteria dated November 2003 relate to primary contact recreation. USEPA indicates that these activities include swimming, water skiing, kayaking, and any other activity where contact and immersion in the water are likely. Swimming and other activities that would likely result in immersion are not permitted uses within the Chicago Waterway System. The access points to the waterways are posted to indicate that the waterways are not suitable for swimming and other activities for which whole body contact would be likely. Three of the signs that indicate that the waterway is unsuitable for swimming and other body contact activities are shown in Figures 4 and 5. Nevertheless, the waterways are accessible at a number of locations. Therefore, some wading and swimming are likely. For example, several of the SEPA (Sidestream Elevate Pool Aeration) Stations are associated with parks. People, particularly children, are likely to be attracted to the cascades. It is possible to wade in the relative shallow water or sit on the concrete structures, thus becoming potentially exposed to microbial contaminants. One of the SEPA stations is shown in Figure 6.





Figure 4. Posted signs on banks of CAWs.



River Safety Precautions

Water quality in the Chicago River system has improved, and more people are using the river for recreation. However, bacteria that can cause illness may be present. Users should take appropriate health and safety precautions.

> Do not swim, dive or wade in the water Do not drink the water Wash hands before you eat or handle food Do not allow pets to drink or play in the water

If boating:

Wear life vests at all times Launch at your own risk, and only at designated launch sites Observe boating rules and regulations

Enjoy the river safely

Call 311 to report debris or illegal dumping

For more information visit www.chicagowaterways.org For fish consumption advisories contact Illinois Department of Public Health, www.idph.state.il.us

Figure 5. Signs cautioning against primary contact activities in the waterways.

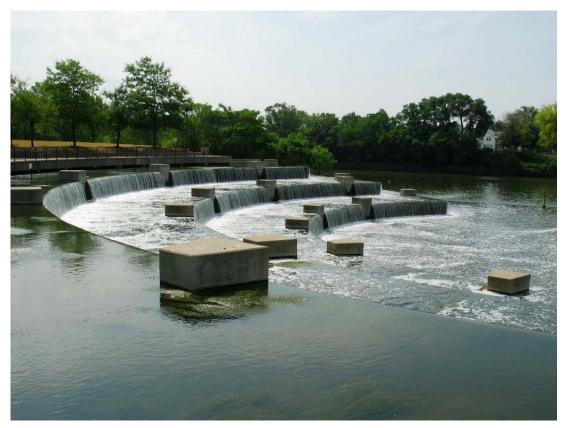


Figure 6. SEPA (Sidestream Elevated Pool Aeration) Station.

During the field visit of the team, we did notice, in addition to secondary contact activity (fishing primarily) at least one kayaker. It would be prudent on the part of the IEPA to determine if modifications in its signage could more effectively discourage such non-swimming primary contact uses of CAWs.

Findings and Conclusions

- F17. One of the activities we noted on our visit (kayaking) fell into the USEPA definition of primary contact, and should be excluded from the CAWs.
- F18. Aesthetically a number of areas of CAWs could be conducive to secondary contact activities at the waters edge.
- F19. There is no direct USEPA guidance relevant to the principal use of CAWs, which is secondary contact.

Recommendations

- R9. IEPA should investigate whether more aggressive signage and/or a change in language could serve as a greater means to discourage kayaking and other primary contact use of CAWs.
- R10. The extent of exposure (for example by splash or aerosols) to the water during secondary contact activities such as fishing needs to be better determined to help define the risk and the approach for determining guideline water quality criteria values for microorganisms.
- R11. The District should consider more aggressive measures to discourage wading in SEPA station pools (including physical barriers and modification in signage).

H. Evaluate use of USEPA's 2003 guidance in the CAWs UAA study.

Given the 5-fold ratio between a primary contact standard and an example secondary contact standard which USEPA cites as being used by several states, the CAWs UAA approach is consistent with USEPA's 2003 document only if kayaking were excluded. However, as noted above, this approach has not been scientifically justified, and therefore the CAWs UAA numbers lack proper foundation.

Findings and Conclusions

F20. The CAWs UAA approach did not appear to make an explicit and detailed consideration of a secondary contact level – and therefore the USEPA recommendation that each jurisdiction evaluate an appropriate secondary criterion did not occur in Illinois.

Recommendations

R12. A detailed determination, following USEPA recommendations, for a secondary contact standard, should be developed by the IEPA for use in a CAWs UAA determination. This should be based on additional water quality monitoring and exposure and health effect information as outlined in the previous recommendations.

I. Summary of Findings and Recommendations

In this section, the findings, conclusions and recommendations enumerated above are recapitulated and grouped into broad topics that may define research and action items for consideration by the District and other interested parties.

Findings and Conclusions

Exposure assessment

F3. USEPA's determination of the single sample maximum for primary contact is based upon an assumed log standard deviation for the indicator (enterococci or *E. coli*) to be used. USEPA has recommended that the log standard deviation be determined by each jurisdiction, which has rarely occurred.

Recreational activities

- F16. Kayaking should be regarded as primary contact with water quality requirements identical to primary contact (swimming) and should not be considered for the CAWs.
- F17. One of the activities we noted on our visit (kayaking) fell into the USEPA definition of primary contact, and should be excluded from the CAWs.
- F18. Aesthetically a number of areas of CAWs could be conducive to secondary contact activities at the waters edge.

Epidemiological & Health

- F1. In the USEPA studies, the strength of association between swimming and illness in the freshwater sites was weak – only two of 9 trials showed a statistically significant difference between swimmers and controls. This may be reflective of the insufficient power of the studies (too few subjects), or high levels of illness in the "control" "nonswimmers".
- F5. There remains a dearth of data on the quantitative relationships between microbial water quality and risk of illness from primary contact recreation in freshwater, however what

data are available supports the use of *E. coli*, and to some degree enterococci in this application.

- F6. There are virtually no data available on which to rationally base criteria for secondary contact recreational exposure, either in freshwater or marine situations.
- F7 In one limited study, individuals who did not fall into the water during boating (Fewtrell *et al., 1994*) reported no adverse health effects when geometric mean fecal coliform levels were below 4613 organisms per 100 mL.
- F8. The freshwater data used by USEPA in establishing freshwater primary contact recreational guidelines were confined to only two lake locations, and their widespread applicability, including to rivers in urban locations may not be appropriate.
- F9. None of the underlying epidemiological studies done to support the USEPA guidelines directly addressed the issues of secondary contact.
- F10. None of the underlying epidemiological studies done to support the USEPA guidelines directly addressed the issues of illness via skin, respiratory, eye or ear routes.

Statistical Analysis

- F11. The USEPA model is not applicable to CAWs and can't be used to produce secondary contact water quality guidelines. A study design is needed to extend the scope of the USEPA model beyond its limited range of application.
- F12. The use of un-weighted log-linear regression to fit the epidemiological studies was not the most appropriate statistical model. The log-logistic model produces better fit, and additionally there is a possible nonlinearity in response, which is difficult to test with the small number of data points.
- F13. In the USEPA analysis, the grouping of all data by swimming season ignores the intraseason variability at a given site³.
- F14. If an adequate epidemiological database pertaining to secondary contact were amassed, then a weighted log-logistic analysis would be appropriate for its analysis.

Regulatory implications

- F2. The determination of enterococci and *E. coli* criteria for primary contact waters given the epidemiologic information determined was appropriate, although (as noted in section D) alternative approaches leading to higher criteria values are also consistent with the data.
- F4. While there is additional data in the form of epidemiological studies of primary contact exposure to freshwater, beyond the Cabelli and Dufour data used by USEPA, it is not clear that these would substantively alter the nature of the conclusions developed by USEPA in 2003.
- F15. The observation by USEPA of prior uses of a secondary contact guidelines of 5x the primary contact guideline is the only federal information to inform water quality criteria in the CAWs, however as noted above, USEPA did not explicitly endorse this but merely mentioned that such approaches have been used by states. This approach needs further investigation to derive a more appropriate jurisdictional limit as recommended by USEPA in its 2003 document.
- F19. There is no direct USEPA guidance relevant to the principal use of CAWs, which is secondary contact.

³ Prior personal communication between CN Haas and Al Dufour suggests, unfortunately, that the raw data to perform an ungrouped analysis is no longer available.

F20. The CAWs UAA approach did not appear to make an explicit and detailed consideration of a secondary contact level – and therefore the USEPA recommendation that each jurisdiction evaluate an appropriate secondary criterion did not occur in Illinois.

Recommendations

Water Quality Studies

R1. To employ the USEPA approach with respect to single sample maxima, site-specific (or at a minimum waterway specific) log-standard deviations should be determined in accordance with USEPA's recommendation (1986 *Ambient Water Quality Criteria for Bacteria*, page 15). This should be based on a well-designed sampling plan encompassing the variability in weather and hydrology encountered.

Epidemiological & Health Studies

- R2. Studies to ascertain risk from secondary contact in freshwater, and the relationship between any such risk and indicator levels need to be conducted. These may be epidemiological studies designed with sufficient statistical power to detect risks at the levels deemed to be acceptable for regulatory purposes. Alternatively, a formal microbial risk assessment can be conducted and more water quality monitoring for a variety of indicators and pathogens is appropriate.
- R4. . Studies to develop criteria for secondary contact, including specifically urban rivers should be conducted. These studies should address multiple exposure pathways.
- R5. Since no information is available in the Cabelli and DuFour data on which to assess the potential or absence of skin, respiratory, eye or ear infection risks resulting from secondary contact, and so if these are deemed of concern for secondary contact, additional studies should be performed to assess their significance.

Data Reanalysis

- R6. Further research is required to develop an appropriate model for analysis of epidemiological data for the purpose of developing guidelines for the CAWs.
- R7. Since the USEPA model has serious limitations as the base for setting the guidelines for primary water contact, more appropriate systematic reanalysis of USEPA and other epidemiological studies to derive criteria using best available statistical models should be undertaken. This should, if possible, not be based on grouping data per swimming season (as USEPA has done), but rather by considering the best estimate of exposure for each individual exposed (and each control individual).

Potentially Exposed Individuals

- R8. To the degree to which kayaking occurs in the CAWs (and during the field visit of the team, we did observe this), the postings should more explicitly warn against this activity, until such time as it is determined, either via risk assessment or epidemiological study specific to the CAWs that the risk to kayakers is acceptable.
- R9. . IEPA should investigate whether more aggressive signage and/or a change in language could serve as a greater means to discourage kayaking and other primary contact use of CAWs.

- R10. The extent of exposure (for example by splash or aerosols) to the water during secondary contact activities such as fishing needs to be better determined to help define the risk and the approach for determining guideline water quality values for microorganisms.
- R11. The District should consider more aggressive measures to discourage wading in SEPA station pools (including physical barriers and modification in signage).

Regulatory Studies and Issues

- R3. A survey of other states and jurisdictions with respect to the rationale for their adoption of secondary contact guideline should be conducted.
- R12. A detailed determination, following USEPA recommendations, for a secondary contact standard, should be developed by the IEPA for use in a CAWs UAA determination. This should be based on additional water quality monitoring and exposure and health effect information as outlined in the previous recommendations.

J. References

- Alexander, LM, Heaven, A. Tennant. A. Morris, R. 1992. Symptomatology of children in contact with sea water contaminated with sewage. Journal of Epidemiology and Community Health. 46: 340-344
- Cabelli, V. J., Dufour, A. P., McCabe, L. J., and Levin, M. A. 1982. Swimming-Associated Gastroenteritits and Water Quality. American Journal of Epidemiology, 115, 606-616.
- Cabelli, V.J. **1983**. *Health Effects Criteria for Marine Recreational Waters*, EPA-600-1-80-031, United States Environmental Protection Agency, Cincinnati, Ohio.
- DuFour, A. P. **1984**. *Health Effects for Criteria for Fresh Recreational Waters*, EPA-600/1-84-004, United States Environmental Protection Agency, Cincinnati, Ohio.
- Fewtrell, L., Kay, D., Salmon, R. L., Wyer, M. D., Newman, G. and Bowering, G. 1994. The health effects of low-contact water activities in fresh and estuarine waters. Journal of the Chartered Institution of Water and Environmental Management 8(1):97-101.
- Fleisher, J.M. 1991. A reanalysis of data supporting U.S. federal bacteriological water quality criteria governing marine recreational waters. Journal of the Water Pollution Control Federation, 63 (3):259-265
- Haas, C.N., Rose, J.B. and Gerba, C.P., 1999. <u>Quantitative Microbial Risk Analysis</u>, John Wiley, New York,
- Pruss, A., 1998. Review of epidemiological studies on health effects from exposure to recreational water. International Journal of Epidemiology 27: (1)1-9
- Stevenson, A.H. 1953. Studies of bathing water quality and health. Amer. J. Public Hlth. 43:530.
- U.S. EPA, January 1986. Ambient Water Quality Criteria for Bacteria—1986. EPA440/5-84-002. Washington DC.
- U.S. EPA, May 2002 Implementation Guidance for Ambient Water Quality Criteria for Bacteria http://www.epa.gov/ost/standards/bacteria/bacteria.pdf.
- USEPA Second National Symposium on Municipal Wastewater Disinfection, Orlando, FL Jan. 26-28, 1982
- Wade, T.J., Pai, N., Eisenberg, J.N.S. and Colford, J.M. 2003. Do U.S. Environmental Protection Agency water quality guidelines for recreational waters prevent gastrointestinal illness? A systematic review and meta-analysis. Environmental Health Perspectives 111(8):1102-1109.

K. Additional Bibliography (not cited in the text)

- Albrecht Wiedenmann, Petra Krüger, Klaus Dietz, Juan M. López-Pila, Regine Szewzyk, and Konrad Botzenhart. **2005.** A Randomized Controlled Trial Assessing Infectious Disease Risks from Bathing in Fresh Recreational Waters in Relation to the Concentration of *Escherichia coli*, Intestinal Enterococci, *Clostridium perfringens*, and Somatic Coliphages, <u>http://ehp.niehs.nih.gov/docs/2005/8115/abstract.html</u>
- Alm EW, Burke J, Spain A. **2003**. Fecal indicator bacteria are abundant in wet sand at freshwater beaches, *Water Research* **37**: 3978-3982.
- AMSA, Comments of the Association of Metropolitan Sewerage Agencies on Water Quality Criteria: Request for Comments, Federal Register, Volume 49, Number 102, Pages 21987 through 21988, Thursday, May 24, **1984**, Association of Metropolitan Sewerage Agencies, Washington, D. C.
- AMSA, Comments of the Association of Metropolitan Sewerage Agencies on Water Quality Standards for Coastal and Great Lakes Recreation Waters (July 9, 2004; 69 Fed. Reg. 41720) (AMSA Comments on the Beach Act Proposal), August 9, 2004, Association of Metropolitan Sewerage Agencies, Washington, D. C
- Byappanahalli M, Fowler M, Shively D, et al. **2003**. Ubiquity and persistence of *Escherichia coli* in a Midwestern coastal stream, *Appl Environ Microbiol* **69**: 4549-4555.
- Byappanahalli MN, Shively DA, Nevers MB, et al. **2003**. Growth and survival of *Escherichia coli* and enterococci populations in the macro-alga *Cladophora* (Chlorophyta) *FEMS Microbiology Ecology* 46 (2): 203-211.
- Byappanahalli, M., M. Fowler, et al., **2003**. Ubiquity and persistence of Escherichia coli in a Midwestern coastal stream, *Appl Environ Microbiol* **69**: 4549-4555.
- Fewtrell, L. 1991. Freshwater recreation: a cause for concern? Applied Geography 11: 215-226.
- Fleisher, J. M. 1992. US Federal Bacteriological Water Quality Standards: A Re-analysis of the Data on Which they are Based, In *Recreational Water Quality Management: Coastal Bathing Waters, ed. D. Kay.* Ellis Horwood. Vol. I: 113-128.
- Fleisher, J. M. and D. Kay, **2006**. Risk perception bias, self-reporting of illness, and the validity of reported results in an epidemiological study of recreational water associated illnesses, *Mar Pollut_Bull* (in press).
- Fleisher, J. M., **1985**. Implications of coliform variability in the assessment of the sanitary quality of recreational waters, *J Hyg (Lond)* **94**: 193-200.
- Fleisher, J. M., **1990**. Epidemiology in transition: a historical hypothesis, *Epidemiology* **1**: 331-332.

Fleisher, J. M., **1990**. The effects of measurement error on previously reported mathematical relationships between indicator organism density and swimming-associated illness: a quantitative estimate of the resulting bias, *International. J. Epidemiol.* **19**: 1100-1106.

- Fleisher, J. M., **1996**. Problems in the average-risk interpretation of categorical dose-response analyses, *Epidemiology* **7**: 211-12.
- Fleisher, J. M., D. Kay, et al., 1996. Marine waters contaminated with domestic sewage: nonenteric illnesses associated with bather exposure in the United Kingdom, Am J Public Health 86: 1228-1234.
- Fleisher, J. M., D. Kay, et al., 1998. Estimates of the severity of illnesses associated with bathing in marine recreational waters contaminated with domestic sewage, *Int J Epidemiol* 2: 722-726.

- Fleisher, J. M., F. Jones, D. Kay, & R. Morano 1993. Setting Recreational Water Quality Criteria, In *Recreational Water Quality Management: Fresh Water, eds. D. Kay and Hanbury*. Ellis Horwood. Vol. II: 123-136.
- Fleisher, J. M., F. Jones, D. Kay, R. Stanwell-Smith, M. Wyer, & R. Morano. 1993. Water and non-water-related risk factors for gastroenteritis among bathers exposed to sewagecontaminated marine waters, *Int J Epidemiol* 22: 698-708.
- Fujioka, R. S., 2001. Monitoring coastal marine waters for spore-forming bacteria of fecal and soil origin to determine point from non-point source pollution." *Water Sci Technol* 44: 181-188.
- Godfree, A. F. Jones, and D. Kay, 1990. Recreational water quality: The management of environmental health risks associated with sewage discharges. *Marine Pollution Bulletin* 21: 414-422.
- Jones, F., and D. Kay, 1989. Bathing waters and health studies. Water Services 93: 87-88.
- Jones, F., D. Kay, R. Stanwell-Smith, and M. D. Wyer, 1990. An appraisal of the potential public health impacts of sewage disposal to UK coastal waters. J. Instit. Water Environ. Man. 4: 295-303.
- Julie Kinzelman, Clement Ng, Emma Jackson, Stephen Gradus, and Robert Bagley. 2003. Enterococci as Indicators of Lake Michigan Recreational Water Quality: Comparison of Two Methodologies and Their Impacts on Public Health Regulatory Events. Appl Environ Microbiol 69:92-96.
- Kay, D., J. Bartram, et al., **2004**. Derivation of numerical values for the World Health Organization guidelines for recreational waters, *Water Res* **38**: 1296-304.
- Kay, D., J. M. Fleisher, et al., **1994**. Predicting likelihood of gastroenteritis from sea bathing: results from randomized exposure, *Lancet* **344**: 905-909.
- Kinzelman, J., C. Ng, et al., **2003**. Enterococci as indicators of Lake Michigan recreational water quality: comparison of two methodologies and their impacts on public health regulatory events, *Appl Environ Microbiol* **69**: 92-96.
- Kinzelman, J., S. L. McLellan, et al., 2004. Non-point source pollution: determination of replication versus persistence of *Escherichia coli* in surface water and sediments with correlation of levels to readily measurable environmental parameters, *J Water Health* 2: 103-114.
- Medema, G. J., A. van Asperen, and A. H. Havelaar. 1997. Assessment of the exposure of swimmers to microbiological contaminants in fresh waters. *Water Sci. Technol.* 35:157-163.
- New Jersey Department of Health, **1988**. A Study of the Relationship Between Illness in Swimmers and Ocean Beach Water Quality. Interim Summary Report, New Jersey Health Department, March 1988.
- New Jersey Department of Health, **1989**. A Study of the Relationship Between Illness in Swimmers and Ocean Beach Water Quality. Interim Summary Report, New Jersey Health Department, March 1989.
- Whitman RL, Nevers MB, Korinek GC, et al. **2004**. Solar and temporal effects on *Escherichia coli* concentration at a Lake Michigan swimming beach, *Appl Environ Microbiol* **70**: 4276-4285.
- Whitman RL, Nevers MB. **2003**. Foreshore sand as a source of *Escherichia coli* in nearshore water of a Lake Michigan beach, *Appl Environ Microbiol* **69**: 5555-5562.
- Whitman RL, Nevers MB. **2004**. *Escherichia coli* sampling reliability at a frequently closed Chicago beach: Monitoring and management implications *Environmental Science & Technology* 38: 4241-4246.

- Whitman RL, Shively DA, Pawlik H, et al. **2003**. Occurrence of *Escherichia coli* and enterococci in *Cladophora* (Chlorophyta) in nearshore water and beach sand of Lake Michigan, *Appl Environ Microbiol* **69**: 4714-4719.
- Whitman, R. L. and M. B. Nevers (2003). "Foreshore sand as a source of Escherichia coli in nearshore water of a Lake Michigan beach, *Appl Environ Microbiol* **69**: 5555-5562.
- Whitman, R. L. and M. B. Nevers, 2004. *Escherichia coli* sampling reliability at a frequently closed Chicago Beach: monitoring and management implications, *Environ Sci Technol* 38: 4241-4246.
- Whitman, R. L., D. A. Shively, et al., 2003. Occurrence of Escherichia coli and enterococci in Cladophora (Chlorophyta) in nearshore water and beach sand of Lake Michigan, *Appl Environ Microbiol* 69: 4714-4719.
- Whitman, R. L., M. B. Nevers, et al. 2004. Solar and temporal effects on Escherichia coli concentration at a Lake Michigan swimming beach, *Appl Environ Microbiol* 70: 4276-4285.