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REPORT OF THE EXPERTS SCIENTIFIC WORKSHOP ON CRITICAL RESEARCH NEEDS FOR THE DEVELOPMENT OF NEW OR REVISED RECREATIONAL WATER QUALITY CRITERIA

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APPENDIX C: TRANSLATION OF EPIDEMIOLOGY TO DISEASE BURDEN BY WHO AND EU

In a series of five international expert consultations that took place between 1996 to 2001, the World Health Organization (WHO), together with partner organizations, including the EPA, the Commission of the European Communities, and a group of independent experts, have developed a methodology for expressing the exposure-risk relationship for recreational water. This approach is outlined in detail in Chapter 4 of the WHO's (2003) *Guidelines for Safe Recreational Water Environments. Volume 1 Coastal and Fresh Waters* (see also Kay et al., 2004). The broad framework is summarized below as a basis for burden of disease calculations.

Stated briefly, the approach is based on the following two assumptions:

1. that the statistical distribution of the fecal indicators (i.e., given a sufficiency of samples through a compliance period such as a bathing season) which predict illness in recreational waters is described by a $\log_{10}$-normal probability density function (pdf); and
2. that the pdf for any beach can be combined with the dose-response curve to produce a unique disease burden for a specific location.

Given a fixed dose-response curve, the relative disease burden (or proportion of the exposed population that becomes ill) for any beach, region or jurisdiction can be calculated from the parameters of the pdf, principally its geometric mean (GM) value (i.e., the mean of the $\log_{10}$ transformed bacterial counts) and the standard deviation (SD) of the $\log_{10}$ transformed bacterial counts. The mathematical basis of these calculations is outlined in WHO (2003), while Kay et al. (2004) and Wyer et al. (1999) provide a discussion on the impacts of different GM and SD assumptions.

Figure C-1 illustrates a theoretical pdf for any beach. The cleaner the water, the further to the left the peak of the pdf will be. Figure C-2 provides the dose response curves reported in Kay et al. (1994) that were used in deriving the standards in WHO (2003). Plot C-2a is projection of the dose-response curve beyond the actual data range of >157 (intestinal) enterococci per 100 mL. In fact, the projection of this relationship to exposures above about 150 enterococci would not be justified because the empirical data acquired during the U.K. randomized sea bathing trials was restricted to lower exposures. Figure Plot C-2b assumes that the excess probability of illness does not continue to increase as enterococci exposure increases above the levels experienced in the sea bathing trials. This was chosen as the dose-response curve in the derivation of the 2003 WHO Guidelines as a pragmatic approach. It should be recognized, however, that it may represent an underestimate of the true disease burden if the curve does not, in fact, flatten as suggested in this diagram.

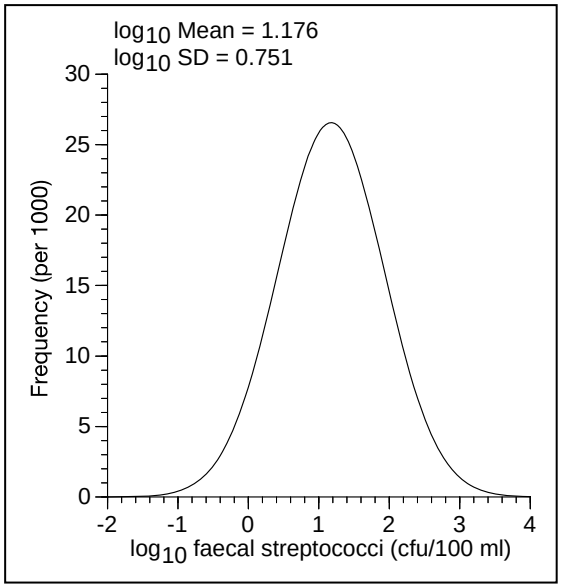

Figure C-1. A Probability Density Function of Fecal Indicator Distributions Measured at a Recreational Water Showing Probability of Exposure (Y Axis) versus Log10 Fecal Streptococci Concentration (later termed enterococci).

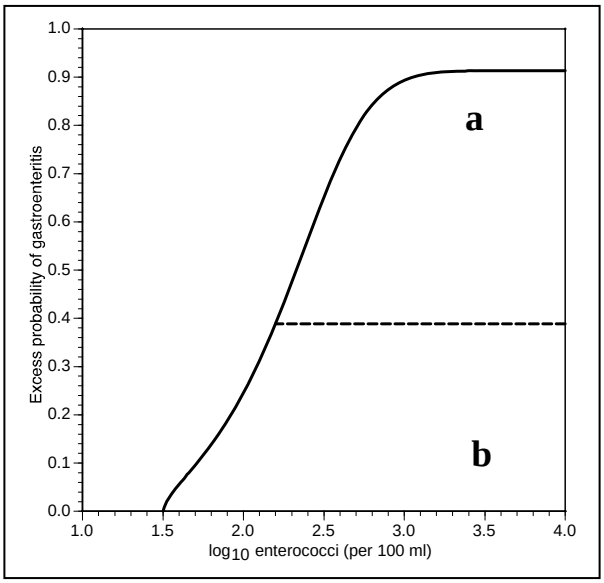

Figure C-2. The Dose-response Relationship Derived From Kay et al. (1994) (a) and the Functional Form Used to Derive the 2003 WHO Guideline Values (b). See Kay et al. (2004) for a more detailed explanation.

Figure C-3 combines the pdf of Figure C-1 with the dose-response curve of Figure C-2 to produce a relative disease burden prediction as a proportion of the exposed population. The mathematical basis of this process is provided in Kay et al. (2004).

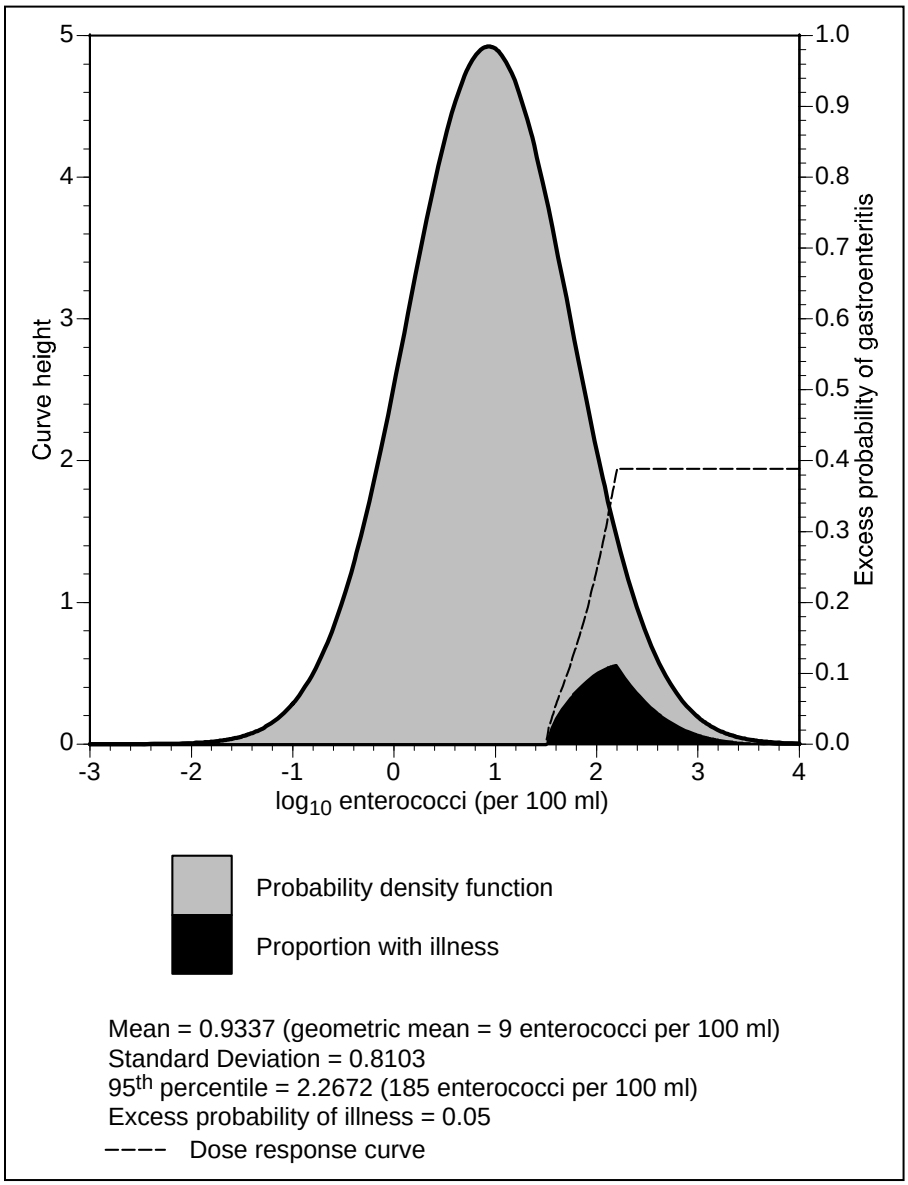

Figure C-3. Combining the Dose-response Curve and the pdf to Produce a Relative Disease Burden Assessment for any Beach or Region.

The computation of gastrointestinal (GI) illness rates in the population is accomplished as follows. The pdf is described by:

$$y = \frac{1}{s\sqrt{2\pi}} e \frac{-(c-m)^2}{2s^2}$$

Where c is the $\log_{10}$ transformed enterococci concentration, y is the normal curve height, and m is the mean enterococci concentration. The associated probability of exposure across a given range of enterococci concentration (i.e., c_a to c_b,) for a given distribution is expressed by:

$$\Phi(c) = \int_{ca}^{cb} y_{dc}$$

which is the area under the normal pdf curve between the limits c_a and c_b. The proportion of bathers with GI illness is then calculated from the area under the curve described by:

$$z = py$$

where p is the probability of GI illness (gastroenteritis) from the dose-response relationship with the upper limit set at 158 enterococci per 100 mL; that is:

$$p = 0.20102\sqrt{(c-31.9)-2.3561}$$

and z is the corresponding proportion of the normal curve height, y. The associated probability of GI illness across the range of enterococci concentrations, c_a to c_b, is then expressed by the following integral:

$$\Phi(c) = \int_{ca}^{cb} z_{dc}$$

For the WHO (2003) Guidelines derivation, the integration of these areas was performed using iterative algorithms as outlined in Khabaza (1965). The algorithm was checked against standard tabulations of the normal pdf curve (Lindley and Miller, 1968) and an accuracy of at least four significant figures was obtained over the specified range of the normal pdf.

References

Kay, D; Fleisher, JM; Salmon, RL; Jones, F; Wyer, MD; Godfree, AF; Zelenauch-Jacquotte, Z; Shore, R. 1994. Predicting the likelihood of gastroenteritis from sea bathing – Results from randomized exposure. *The Lancet* 344: 905-909.

Kay, D; Bartram, J; Pruss, A; Ashbolt, N; Wyer, MD; Fleisher, JM; Fewtrell, L; Rogers, A; Rees, G. 2004. Derivation of numerical values for the World Health Organization guidelines for recreational waters. *Water Research* 38: 1296-1304.

Khabaza, IM. 1965. *Numerical Analysis*. London: Pergamon Press.

Lindley, DV; Miller, JCP. 1968. *Cambridge Elementary Statistical Tables*. Cambridge: Cambridge University Press.

WHO (World Health Organization). 2003. *Guidelines for Safe Recreational Water Environments. Volume 1 Coastal and Fresh Waters.* Geneva, Switzerland: WHO.

Wyer, D; Kay, D; Fleisher, JM. 1999. An experimental health-related classification for marine waters. *Water Research* 33(3): 715-722.