



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

EPA-SAB-DWC-LTR-92-011

Honorable William K. Reilly
Administrator
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Subject: Review of the Drinking Water Criteria Document for
Cryptosporidium

Dear Mr. Reilly:

The Drinking Water Committee (DWC) of the Science Advisory Board (SAB) met on February 11-12, 1992 and reviewed the Drinking Water Criteria Document for Cryptosporidium.

Overall, the Drinking Water Committee considers the draft document to be inadequate as a criteria document. This is because of the following deficiencies: 1) it does not reflect the current state of knowledge; 2) it is superficial in its coverage of information on Cryptosporidium in drinking water and the aquatic environment, especially concerning treatment efficacy; 3) it does not identify the important gaps in scientific knowledge and understanding of Cryptosporidium or its public health significance in drinking water; 4) it does not identify the scientific needs that must be met to go forward with a risk assessment; and 5) it draws no conclusions and makes no recommendations on future scientific directions to decide if Cryptosporidium in drinking water should be regulated and if so, how to regulate it.

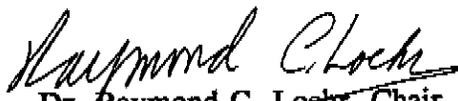
The Drinking Water Committee recommends a revision of this Draft Criteria Document on Cryptosporidium in Drinking Water that is responsive to the deficiencies and errors noted in this review. A comprehensive revision of the document is necessary in order to move forward with a scientific risk assessment and risk characterization. The revision should include an insightful and critical analysis of the following topics: 1) the organism and its diseases in humans; 2) the sources and occurrence of the organism in water and the role

of water in its transmission; 3) the efficacy of water treatment processes for its removal and inactivation; and 4) the risk of drinking water as a source of human exposure, infection and illness. The revised document should identify and prioritize the gaps in current scientific knowledge that must be filled in order to conduct a comprehensive risk assessment according to a systematic conceptual framework. A desirable conceptual framework includes the following key points: hazard identification, exposure assessment, effects assessment based on dose-response and epidemiological data, risk assessment and risk characterization, and finally, the scientific basis on which to proceed with risk modelling, quantitative risk analysis, and the known relative risks (compared to disinfectants and disinfection by-products).

The sections of the document that concern *Cryptosporidium* in water and elsewhere in the environment are lacking in both detail and important scientific information that is already available. A significant document that is more comprehensive and more analytical about *Cryptosporidium* in drinking water has already been published in Great Britain, but this document was cited only superficially (Badenoch, J. (1991) *Cryptosporidium* in Water Supplies. HMSO, London). The Drinking Water Committee believes that the British document is a much better source of information than the draft document under review. The British document contains important conclusions and recommendations that should have been considered in this draft criteria document.

Thank you for the opportunity to review this draft criteria document and to provide the above advice. In addition, we have included specific comments as an attachment to this letter. We look forward to your response to the advice contained in this letter.

Sincerely,


Dr. Raymond C. Loehr, Chair
Science Advisory Board


Dr. Verne Ray, Chair
Drinking Water Committee

Attachment

Specific Comments and Questions

Page 2, second paragraph, line 1. It is stated that the cryptosporidium organisms are 2-6 micrometers in diameter. However, there is evidence that the range of diameters may be greater than this.

Page 2, second paragraph, lines 5 and onward. Cryptosporidium was more than a "curiosity" and was recognized as an important pathogen in cattle before 1980.

Page 3, 2nd paragraph. The information here concerning sources of exposure (human versus animal) and transmission routes are unclear and maybe misleading. Both humans and some other animals, such as cattle, are important reservoirs of the organism. Modes of transmission include person-to-person, animal-to-person, and fecally contaminated vehicles, including water. The airborne route of exposure, if it occurs in humans, must be documented, because the fecal-oral route is the only one generally recognized. The relative importance or significance of these different exposure routes is variable and uncertain, because it depends on population, location, environment and other demographic factors.

Page 3, paragraph 4. This paragraph is poorly written because it includes too many topics that should be presented separately and more clearly. The paragraph covers susceptibility, clinical illness, and resistance in both normal and immunosuppressed or immunodeficient persons. The paragraph also includes occurrence (prevalence and incidence) data, which are presented unclearly and incompletely. They should be presented more clearly and comprehensively in a separate paragraph.

The importance and significance of respiratory infection and illness must be addressed more clearly in this document. It is not clear that respiratory transmission occurs, and the significance of respiratory illness (as seen in immunosuppressed individuals) relative to exposure from drinking water is also unclear.

Page 4, paragraph 3. The outbreak in Texas was not conclusively proven to be cryptosporidiosis. A virus (Norwalk virus) was also involved. Furthermore, it is uncertain that coliform bacteria were adequately controlled at the time of this outbreak. Coliforms were not detected, but this does not prove that they were being adequately controlled when the likely exposure to contaminated water was occurring.

Page 5, 2nd paragraph, last sentence. It is implied that many other waterborne outbreaks of *Cryptosporidium* have occurred. These are not documented, detailed or discussed. If there are many such outbreaks, then their characteristics and the circumstances surrounding their occurrence should be detailed.

Page 5, 3rd (last) paragraph, 1st sentence. Data from one survey (not referenced) are presented here. There have been other surveys. A more representative summary of all survey data should be given.

Page 6, 3rd paragraph. The similarities between *Cryptosporidium* and *Giardia* are largely superficial, and so this paragraph should be re-worded to make that clear. The paragraph should also be re-worded to state more clearly the purpose of the SWTR (it regulates other microbes besides *Giardia*). It should make clear that the treatment requirements for *Giardia* cannot be applied to or interpreted for *Cryptosporidium* because of a lack of occurrence and treatment data on *Cryptosporidium*. The last sentence of the paragraph implies that there is sufficient knowledge (data) to suggest that *Cryptosporidium* is reduced less effectively than *Giardia*. This is not the case.

Pages 6-12. Taxonomy. The potential significance of *C. bailevi* also should be highlighted, given the recent evidence of human infection (Ditrich et al., *Parasit. Res.*, 77:44-47, 1991.).

Page 42, 3rd (last) paragraph. The possibility of other sources of exposure in purported waterborne outbreaks should be better documented. If such misclassification of exposure routes or sources of exposure occurs, a tabulation of these outbreaks, giving the different possible routes of exposure for each outbreak, would be useful.

Page 49, 1st paragraph, 1st sentence. The seasonality of *cryptosporidium*, as explained here, is unclear. Either more detailed and persuasive information must be presented (or cited) or the issue of seasonality must be left as being inadequately characterized in the U.S.

Page 55, Quantitative Risk Assessment. The coverage and treatment of the infectious dose aspects of *Cryptosporidium* are much too limited. If there are inadequate dose-response data to determine the size of an infectious dose corresponding to a certain risk of infection, this should be clearly stated. Additionally, the need for such data from humans and other animals should be emphasized as a gap in essential scientific information and hence, a research need.

If there are greater risks (of infection and death) to immunocompromised hosts, as is stated later in this paragraph, than what is the effect of immunosuppression or immunodeficiency on dose-response relationships for *Cryptosporidium*?

Page 57, 1st paragraph, last sentence. What is the basis for saying that the southeastern U.S. has a greater risk of waterborne cryptosporidiosis? No documentation is provided for this statement.

Page 57, 2nd paragraph, last 2 sentences. No substantive and quantitative documentation are provided for the statements on the risk of exposure to *Cryptosporidium* from filtered water supplies, the expected 2 log removal by filtration, the evidence that surface waters contain "high" levels of oocysts (either spatially or temporally) and that " approximately 134 million additional people are at risk of exposure". If this represents some sort of quantitative or even qualitative risk assessment, it must be better documented. Otherwise, the statements are not justified on the basis of the scientific data or analyses presented.

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