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MERCK
Manufacturing Division

December 19, 2008

Environmental Quality Board
P.O. Box 8477
Harrisburg, PA 17105-8477

Subject: Comments on Proposed Rulemaking, Safe Drinking Water (Groundwater Rule)

Ref: 38 PA Bulletin 6483, November 29, 2008

Dear Environmental Quality Board:

The West Point, PA site of Merck & Co., Inc. (Merck) appreciates the opportunity to submit comments on the Safe Drinking Water Act proposed rulemaking as published in the November 29, 2008 PA Bulletin.

The Merck – West Point, PA site operates a nontransient noncommunity public water supply, PWS ID No. 1461065, which maintains continued compliance with all state and federal drinking water standards and regulations.

Comments:

The U.S. EPA groundwater rule (GWR) was promulgated on November 8, 2006. The proposed PA GWR is, for the most part, consistent with the requirements of the U.S. EPA GWR. The PA GWR is more stringent than the EPA GWR with triggered monitoring requirements (section 109.1303), however. Triggered monitoring requires monitoring of source water for *E. coli* whenever a public water system that cannot or has not demonstrated 4-log treatment of viruses receives a distribution system total coliform detection. The EPA GWR states that source monitoring for *E. coli* is not required if the total coliform detection is related to a distribution system deficiency (40 CFR 141.402(a)(5)). The PA GWR does not allow for this exception. In preamble language for section 109.1303, DEP states, "the Department does not believe it is possible to eliminate source water quality as a potential source contributor to the distribution contamination without additional sample results." Merck disagrees. This statement from the preamble, and DEP's direction with triggered monitoring, not only conflicts with existing regulation in Chapter 109 (109.301(3)(ii)), but also conflicts with bacterial science, and with the operational engineering of a drinking water supply system.

Total coliform is the primary indicator organism for evaluating the bacterial safety of drinking water. The test is relatively inexpensive and easy to perform. Total coliform is a collective group of other possible indicator organisms of drinking water bacterial testing. Two others include fecal coliform which is a type of total coliform and mostly exists in feces, and *E. coli*, which is a type of fecal coliform bacteria. Total coliform bacteria are commonly found in the environment and are generally harmless. In bacterial testing of drinking water, if total coliform is detected and no other bacterial organisms, then a fecal contamination source is highly unlikely. Intestinal pathogens cannot survive outside of the body and are not commonly found in groundwater, unless the well is too shallow, or improperly constructed or damaged.[1] In addition,

[1] B. Daniels, N. Mesner. Drinking Water Facts: Coliform bacteria. Utah State University, Water Quality Extension. June 2005.

the most likely sources of coliform bacteria in a drinking water system are from the points of use (spigot, sink), from improper backflow protection from a contaminated source, and from reduced pressure in underground water lines resulting in drawing in soil water at joints.[2] Existing chapter 109 regulations support the information presented in this paragraph.

Section 109.301(3) provides the monitoring requirements for coliform. This section mandates the number of samples that must be taken based on population served. Populations greater than 1000 people require multiple samples (more than one) per monitoring frequency. In addition, section 109.301(3) specifies the requirements in response to a total coliform positive sample. A total coliform positive sample requires repeat monitoring for either fecal coliform or *E. coli*, and check samples at, upstream, and downstream of the total coliform positive sample location. These existing regulations clearly paint a picture of: (a) recognition that a single total coliform positive sample does not necessarily translate into a system-wide or source level fecal contamination issue, and (b) the source is likely distribution system based, but must first be confirmed through additional distribution system sampling. The existing regulations provide a systematic methodology of locating the source of the total coliform positive result, or in fact obtaining data that will invalidate the total coliform positive result. In addition to the section 109.301(3) regulations, DEP's Tier 2 public notice requirements under section 109.409 state that for a total coliform MCL exceedence when fecal coliform or *E. coli* is not present, the water system is allowed up to thirty (30) days to issue a public notice. This lengthy amount of time for public notification provides clear indication of DEP's recognition that when only total coliform is present in the distribution system, there is a low immediacy of health risk to the population served.

These discussions lead to the point that the proposal in section 109.1303 requiring *E. coli* sampling of all water sources as a result of a single total coliform positive sample in the distribution system is an unsubstantiated and overly conservative leap.

The Merck-West Point potable water supply is a specific example. A block diagram of the system is attached. The Merck potable water system is a permitted nontransient noncommunity water supply that meets the needs of the 8500 employees as well as all industrial, laboratory, and utility water needs. The water sources for the system consist of twelve (12) wells owned and operated by Merck, and an interconnection with the local municipal water supplier, with, on average, fifty percent of site water needs coming from each. Based on 109.301(3) requirements and a site employee population of 8500, Merck is required to sample ten (10) distribution system locations each month for total coliform. Merck has chosen to also sample each total coliform location for *E. coli*. As an example, assume one of the total coliform sample sites yielded a positive result, the other nine were negative, and all ten sample results for *E. coli* were negative. Under 109.301(3), Merck has already met the requirement to sample for fecal coliform or *E. coli*. Under this section, Merck is also required to analyze three (3) check samples for total coliform. The results of these check samples will be used to determine compliance with the coliform MCL, help determine a source, and possibly be used to invalidate the original total coliform positive sample. Since Merck proactively analyzes for *E. coli*, the initial conclusion of these sample results is that this is an isolated total coliform-only event, there are no fecal coliform contamination concerns, and sampling of the water sources for *E. coli* is not necessary. Even if Merck did not proactively sample for fecal coliform or *E. coli*, a repeat sample that is negative for fecal coliform or *E. coli* would provide the same conclusion that there is not a fecal coliform contamination concern, and therefore, sampling the water sources, whether wells or municipal connection, is not necessary even if the original total coliform positive sample was valid.

This is not a stretch example, but is the standard scenario for a water supplier with groundwater sources. As was previously stated, intestinal pathogens are not common in groundwater (Daniels 2005), and the most common sources of coliform in a water supply is the distribution system itself (National Ground Water Association, 2008). In addition, a coliform contaminated groundwater

[2] Wellowner.org. Bacteria: What Do You Want to Know? National Ground Water Association, 2008.

source would result in system-wide total coliform positive results and not a single positive sample result.

The above example also points out another disparity in the proposed PA GWR. Section 109.1303(a) states, "Groundwater systems not required to conduct compliance monitoring under 109.1302.....shall collect a source water sample for *E. coli* within 24 hours of notification of a total coliform-positive sample collected under 109.301(3)." As has been previously presented, 109.301(3) has a number of its own requirements following notification of a total coliform positive sample, including repeat sampling for fecal coliform or *E. coli* and analysis of multiple check samples. 109.301(3) also provides for the evaluation of sample results for possible invalidation of the original total coliform positive sample. The proposed rule preamble language for section 109.1303 recognizes the total coliform positive sample invalidation process. The disparity, therefore, exists in the timing requirements of the proposed rule (24 hour response) and the amount of time required to complete the requirements in the existing 109.301(3). The proposed PA GWR does not change any of the existing requirements in 109.301(3). Therefore, when a water supplier receives a total coliform positive sample result, per regulation they are still required to meet the requirements of section 109.301(3) which must be performed within 24 hours of notification. But according to the proposed 109.1303(a), sampling of water sources must be completed within 24 hours of a valid total coliform positive sample. Therefore, it appears that section 301(3) requirements must first be performed, with section 1303(a) requirements being initiated within 24 hours of data validation. But this is not clear and extremely confusing as currently presented in the proposed PA GWR.

In conclusion, Merck requests that:

1. Section 109.1303 be modified to be consistent with the EPA GWR. Specifically, modify section 109.1303(a) to state that sampling of water sources is required for a valid total coliform positive result within 24 hours of determining that the total coliform-positive sample is not conclusively related to a distribution system source in accordance with technical guidance developed by DEP.
2. PA DEP develop a technical guidance document for evaluating total coliform-positive results for public water suppliers with groundwater sources to determine or refute direct relationship to the distribution system, and establishing and communicating decision criteria for source sampling under section 109.1303(a). A workgroup of technical representatives from PA water suppliers with groundwater sources could be utilized to help identify key criteria for the document.

Merck appreciates the opportunity to comment on this proposed regulation. If you have any questions, please do not hesitate to contact me at (215) 652-7973, or robert_cavett@merck.com.

Sincerely,

Robert Cavett
Senior Environmental Engineer

Attachment

cc: Alice L. Lenthe, P.E., Director, WP Safety and Environmental Management

MERCK - WEST POINT, PA
POTABLE WATER SYSTEM