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MERCK

February 1, 2010

Environmental Quality Board
400 Market Street
Rachel Carson State Office Building, 16th Floor
Harrisburg, PA 17105-2301

Subject: Comments on Proposed Rulemaking, Wastewater Treatment Requirements, 25 PA Code Ch. 95

Ref: 39 PA Bulletin 6467, November 7, 2009

Dear Environmental Quality Board:

The West Point, PA site of Merck Sharp & Dohme Corp. (Merck) appreciates the opportunity to submit comments on the proposed rulemaking for 25 PA Code Chapter 95, Wastewater Treatment Requirements, as published in the PA Bulletin on November 7, 2009 and corrected in the November 14, 2009 PA Bulletin.

Merck's West Point, PA plant is a pharmaceutical and vaccine research, development, and manufacturing facility. With a work force of approximately 8,500, West Point is Merck's largest facility for the discovery and development of life saving and life enhancing drugs. A number of significant vaccines are manufactured at West Point, including MMR for the prevention of measles, mumps, and rubella in children, GARDASIL for prevention of cervical cancer in women, and ROTATEQ for prevention of rotavirus gastroenteritis in infants. The West Point plant discharges treated process and domestic wastewater to the Wissahickon Creek through the Upper Gwynedd Township wastewater treatment facility and to Towamencin Creek through the Upper Gwynedd-Towamencin Municipal Authority.

As a member of the Water Resources Advisory Committee (WRAC) and the PA Chamber of Business and Industry, Merck has been actively involved in WRAC and the Chapter 95 Total Dissolved Solids (TDS) Task Force regarding the proposed TDS wastewater treatment issue.

Comments:

1. Through the proposed rulemaking, the Department is proposing a statewide end of pipe technology-based standard for new, additional, expanded, or increased discharges of TDS that exceed either 2,000 mg/l or 100,000 pounds per day. These high TDS dischargers must comply with the following discharge limits:
   a. TDS: No greater than 500 mg/l monthly average
   b. Total chlorides: No greater than 250 mg/l monthly average
   c. Total sulfates: No greater than 250 mg/l monthly average

   Even though DEP has made a number of presentations to WRAC and the TDS Task Force since April 2009, the Department has not demonstrated a justification for this statewide standard based on the data presented. Members of the Task Force have repeatedly stated to DEP that the issue is limited to three stream segments, with only one (Monongahela River) showing any potential violation of the current Chapter 93 standard for TDS. The data for the other two streams points to potential depletion of the streams' assimilative capacity, but not an exceedence of the current chapter 93 TDS standard. The data presented by DEP represents a fraction of the Commonwealth's 86,000 miles of streams, and are

indicative of localized watershed-specific issues. The data does not support the statewide wastewater treatment requirement that is proposed.

2. The proposed TDS applicability thresholds (2,000 mg/l or 100,000 pounds per day), defining a "high-TDS discharger," are not based on sound scientific rationale or methodology. These thresholds do not account for any consideration of stream flow, discharger flow, TDS background levels, and proximity to public water supplier intakes (the regulated point of TDS compliance). Furthermore, use of the concentration-based threshold (2,000 mg/l) by itself presents a very significant issue to small dischargers without any notable benefit to the receiving stream or affected public water supply intakes. For example, for a discharger to obtain a TDS mass loading of 100,000 pounds per day and an effluent TDS concentration of 2,000 mg/l, the discharge flow would have to be 6 million gallons per day. A small industrial flow of 200,000 gallons per day that happened to have an effluent TDS concentration of 2,000 mg/l would only be discharging 3,340 pounds of TDS per day, which is substantively less than the alternative mass-based loading threshold of 100,000 pounds per day. The determination of a high, or problematic, TDS discharger must be based on all of the necessary parameters for determining environmental impacts, and the actual mass loading of TDS.

3. Likewise, the discharge limits proposed for high-TDS dischargers did not consider the many technical and regulatory parameters and variables that are typically included in calculating discharge limitations (e.g. flows, background levels, proximity to regulated points of compliance, environmental chemistry of the parameter, etc). TDS is a combined measure of inorganic and organic materials in water that are, generally speaking, small enough to pass through micron-size filtration. TDS most commonly consists of a number of cations and anions such as chlorides, sulfates, phosphates, calcium, sodium, etc. Sources of TDS in water vary from point sources, such as industrial or sewage treatment plant discharges, nonpoint sources such as nutrients from agricultural or residential storm water runoff or storm water runoff from roads following winter de-icing, and naturally-occurring background levels, such as from local geology. Current PA water quality standards have in-stream standards for TDS, chlorides, and sulfates which are enforced at the inlet to public water suppliers (PWS). Since the data presented by DEP does not indicate a statewide TDS issue, and the proposed limits are not based on real in-stream TDS considerations, these limits being imposed on PA commerce and industry are not actually fixing an environmental compliance problem for a majority of the Commonwealth. Conversely, the proposed discharge limits are overly conservative and overly protective because they apply discharge limits to dischargers whose effluent is not currently degrading inlet TDS levels at a PWS. Industrial and municipal dischargers will have to incur significant economic impacts to meet discharge limits that do not have an environmental benefit for most of PA.

4. The Department stated in a few meetings that the proposed rulemaking and associated discharge limits will assist in ensuring the current in stream standard for osmotic pressure (50 milliosmoles per kg maximum) is maintained. DEP, however, failed to provide data demonstrating a statewide problem with meeting the in stream osmotic pressure standard. In addition, the Department did not provide information on the specific quantifiable relationship between the proposed discharge limits and the current osmotic pressure standard.

   Simplistically, increased TDS loadings in water increase the osmotic pressure in the water. Mathematically, osmotic pressure in a liquid can be approximated using the Morse equation, which gives the pressure on one side of a membrane:

   Osmotic pressure (atmospheres) = iMRT

   i is the dimensionless van't Hoff factor
   M is the molar concentration of the contributing material
   R is the gas constant
   T is temperature in degrees Kelvin

The final calculation is converted to milliosmoles by the following conversion factor:

1 milliosmole = 0.0224 atm

According to the Morse Equation, an in stream TDS concentration of almost 1600 mg/l at 20° C, consisting of sulfates and chlorides, would equate to an osmotic pressure of 50 milliosmoles, which is the current Chapter 93 standard for osmotic pressure. The Morse Equation, however, is limited in its accuracy and applicability to in stream TDS levels because of the varied composition of minerals that comprise TDS and their impacts with respect to ion balances in aquatic organisms. The most appropriate evaluation of a discharger's potential aquatic impact is the Whole Effluent Toxicity Test (WETT) which many permitted dischargers in PA are already required to do, and not a TDS discharge limit.

5. The proposed Chapter 95 regulation penalizes dischargers that pursue water conservation at their facilities, and conflicts with PA water conservation efforts as presented in section 3120 of the PA Water Planning Act. Water conservation and efficiency increases the concentration of TDS in the final effluent. The proposed regulation under 95.10 would consider such increases in TDS concentration as a new or increased TDS source, thus triggering the proposed TDS requirements. The current focus on concentration penalizes companies who want to do the right thing and decrease water usage, and is a disincentive for water conservation and efficiency. The cost to treat TDS would far exceed any monetary savings achieved from water conservation.

6. The Department did not consider the significant economic and adverse environmental impacts of the proposed regulation. PA dischargers will incur considerable expenses, produce substantive solid (brine) waste, and use considerably more energy, thus increasing air pollution, to comply with a regulation that does not increase compliance with the current Chapter 93 TDS criteria for a majority of PA rivers and streams.

   As a specific example, the primary sources of TDS at Merck are cooling tower blowdown and the use of acids and bases for manufacturing and research equipment cleaning. Merck has maximized the number of cooling tower concentration cycles due to advanced cooling tower chemical treatment, which reduces the volume of cooling tower discharge. The use of acids and bases for process equipment cleaning is prescriptively mandated by another government agency (U.S. Food and Drug Administration) to meet sterility requirements. Since Merck's cooling tower operations are already optimized, and process cleaning operations are mandated by another regulatory agency, the only option is to treat site effluent to achieve the proposed TDS local limit. The proposed wastewater treatment technology is reverse osmosis. The capital cost for installation and startup of a reverse osmosis system and associated pretreatment system to treat Merck's wastewater effluent to a TDS level of 500 mg/l is $13.2 million. The annual operating cost, minus waste disposal and energy costs, is $4.9 million. The waste generated from this treatment system consists of 7.2 tons (~6 cubic yards) per day of salt brine at a disposal cost of $263,000 per year. The energy required to operate the treatment system is 7.3 million kW-hours per year at an annual electric cost of $400,000.

   The adverse environmental impacts from this reverse osmosis treatment system are significant. Disposal of the brine waste will require the services of an out-of-state disposal facility, resulting in daily truck traffic in excess of 80 miles per day, for an increase in diesel fuel consumption of up to 6000 gallons per year and the resulting air pollution emissions from that fuel consumption. The increased electrical energy use of 7.3 million kW-hours per year will result in an increase in NOx emissions of 5,000 pounds (2.5 tons) per year, and an increase in carbon dioxide emissions of 4 million pounds or 2,000 tons per year.

   Merck fully realizes the costs of doing business in Pennsylvania that are necessary to protect the environment and comply with regulations. But the increased business costs and corresponding secondary environmental impacts cited above are not necessary to maintain continued compliance with the PA TDS standards or protect local PWS inlets. Specifically, the local receiving stream does not

have a PWS located on it. The closest affected PWS is twenty miles downstream, located on a major river system after the confluence point with the local receiving stream. The PWS has never indicated a problem with inlet TDS levels. Using the 7Q10 stream flows at both the local receiving stream and the PWS inlet, a TDS treatment system that costs over $13 million to install, over $5 million per year to operate, and results in 2,000 tons per year of increased carbon dioxide emissions due to electrical demand would reduce the TDS levels at the PWS inlet by only 9 mg/l, at a PWS where reduced TDS inlet levels are not necessary.

This is exactly the kind of scenario that results in senior industry officials throughout Pennsylvania questioning the economic viability of establishing facilities in the Commonwealth.

Recommendations:

1. Merck recommends that PA DEP abandon the proposed Chapter 95 wastewater treatment proposed rulemaking.
2. Merck recommends that PA DEP specifically identify the limited number of streams and rivers in PA that face potential TDS non-compliance in accordance with the current Chapter 93 criteria for TDS. DEP should identify the sources of TDS causing the TDS issues and regulate those sources in accordance with their existing regulatory authority.
3. For streams and rivers demonstrating potential TDS assimilative capacity depletion:
    a. Establish a "Trigger Point" for identifying target watersheds facing potential assimilative capacity issues at the current Chapter 93 TDS standard and point of compliance (PWS inlet) under low flow conditions. Merck suggests a trigger value of 75% of the watershed's assimilative capacity. Assessment of the watershed's assimilative capacity would be based on actual and projected TDS loadings over a defined time period (e.g. five years, the standard time period of an NPDES permit). Water quality data should be based on information obtained from NPDES permits, DMR data, permit applications, and actual water quality monitoring data.
    b. For watersheds that are assessed as exceeding the established trigger point, DEP will develop and implement a watershed management plan for managing TDS levels in that watershed. The watershed management planning process should involve major dischargers and stakeholders. The outcomes of the watershed management plan must identify significant TDS sources and loadings, and establish an action plan to manage TDS loadings in the watershed and avoid exceeding established TDS water quality criteria.

Merck does not dispute or invalidate that total dissolved solids are, or could be, an issue for certain watersheds in Pennsylvania. Our point is that the data does not support TDS as being a widespread problem throughout the Commonwealth, and the current proposed rulemaking will damage the PA economy without accomplishing any environmental compliance gains for a majority of the state. We request that DEP let the data focus their efforts on managing actual in-stream TDS concerns while keeping PA business and industry economically competitive.

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

cc: Alice L. Lenthe, P.E., Director, West Point Safety and Environment