

EPA National Cases of Interest



**U.S. Environmental
Protection Agency**

Region 8

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The “pH” in Pharmaceutical: BioMarin Enforcement Case

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Background:

- BioMarin
 - A pharmaceutical manufacturer that specializes in producing enzymes
 - Multi-national, multi-million dollar company based in Novato, CA
 - An industrial user (IU) that discharges to the Novato Sanitary District's collection system and Ignacio Wastewater Treatment Plant



Location: Novato, CA



EPA Audit:

- Accompanied the contractor – TetraTech – on an audit (PCA) of Novato Sanitary District, May 2, 2007.
- Typical format includes:
 - interview of pretreatment coordinator
 - file reviews of select IUs
 - facility inspections of select IUs
- BioMarin was one of the selected IUs.



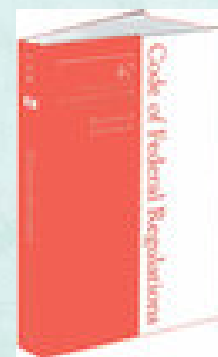
Audit Findings:

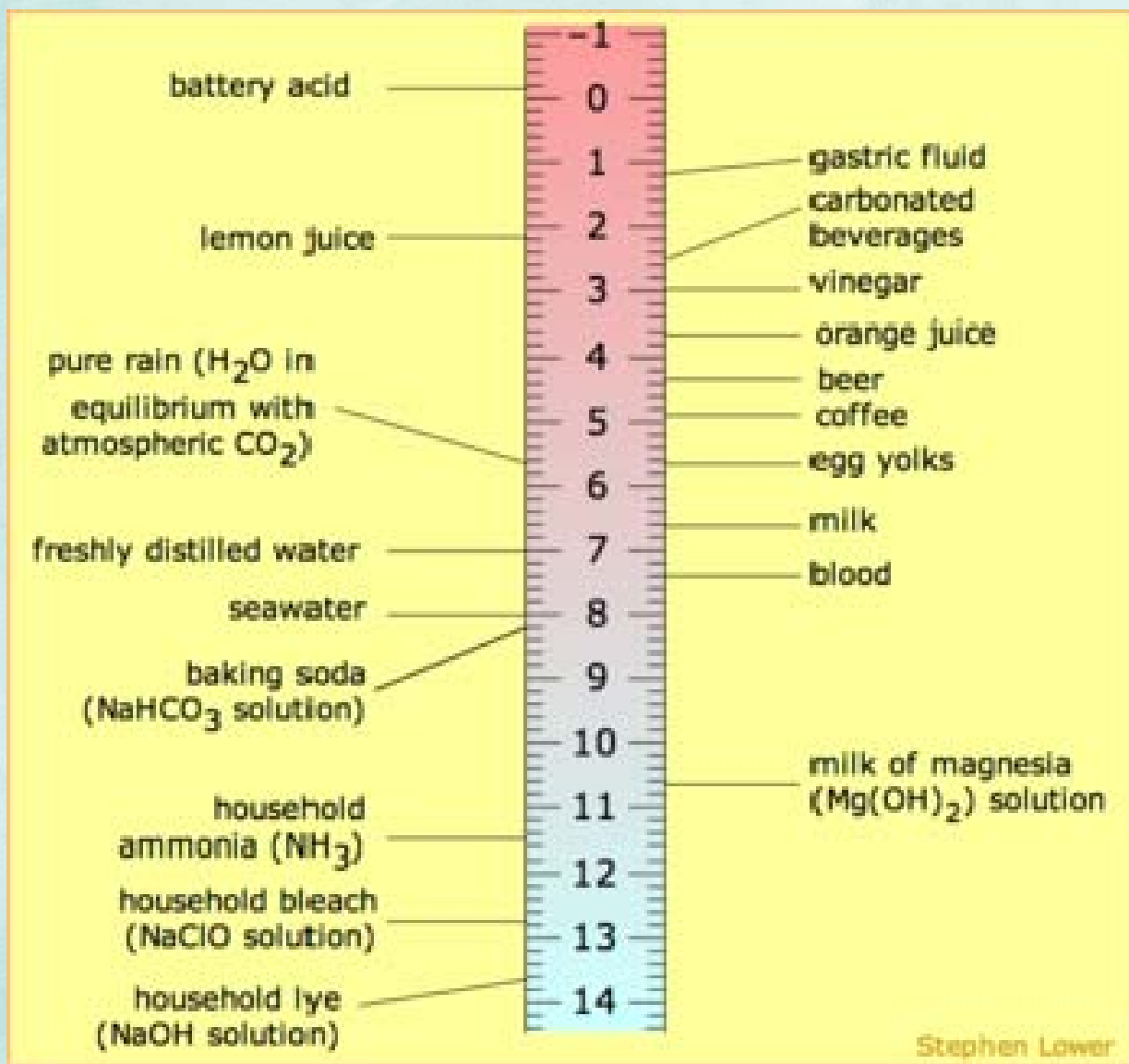
- Numerous violations over the years of pH and BOD permit limits
- District (Approved Programs) Actions:
 - BOD
 - NOVs and an administrative order
 - Surcharge fee for the extra BOD loading on the treatment plant
 - pH – An NOV for each violation



Regulations:

- Pretreatment standards
 - Govern the introduction of industrial pollutants into POTWs
 - Set of specific prohibitions (40 CFR 403.5)
 - One of these is the prohibition of pollutants that will cause corrosive structural damage to the POTW, and in no case can the pH be less than 5.0



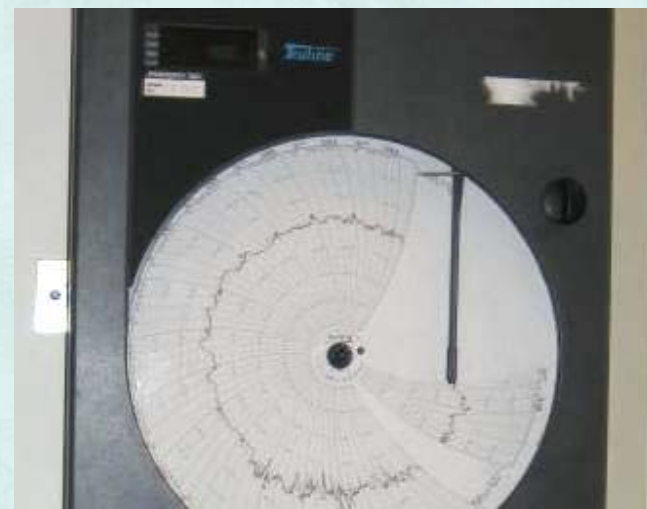


Stephen Lower



Violations:

- Violations at Manufacturing Facility
 - EPA reviewed BioMarin's monitoring records Jan 2004 – Dec 2007.
 - Violated federal pH prohibition a total of 62 days.
 - $\text{pH} < 5.0$ at any time.



Violations:

- Mostly short-duration events occurring almost each month of the year
- Some violations considered hazardous ($\text{pH} < 2$).
- BioMarin's reasons for violations: primarily personnel error
 - Triple rinsing acid containers - release of rinse solution to sanitary sewer
 - Clean room sanitization – disposal of low-pH cleaning solution down the drain



Why did EPA become involved?

- High number of violations of a federal pretreatment standard (62 Days).
- Lack of escalation of enforcement by the control authority (ERP not being followed)

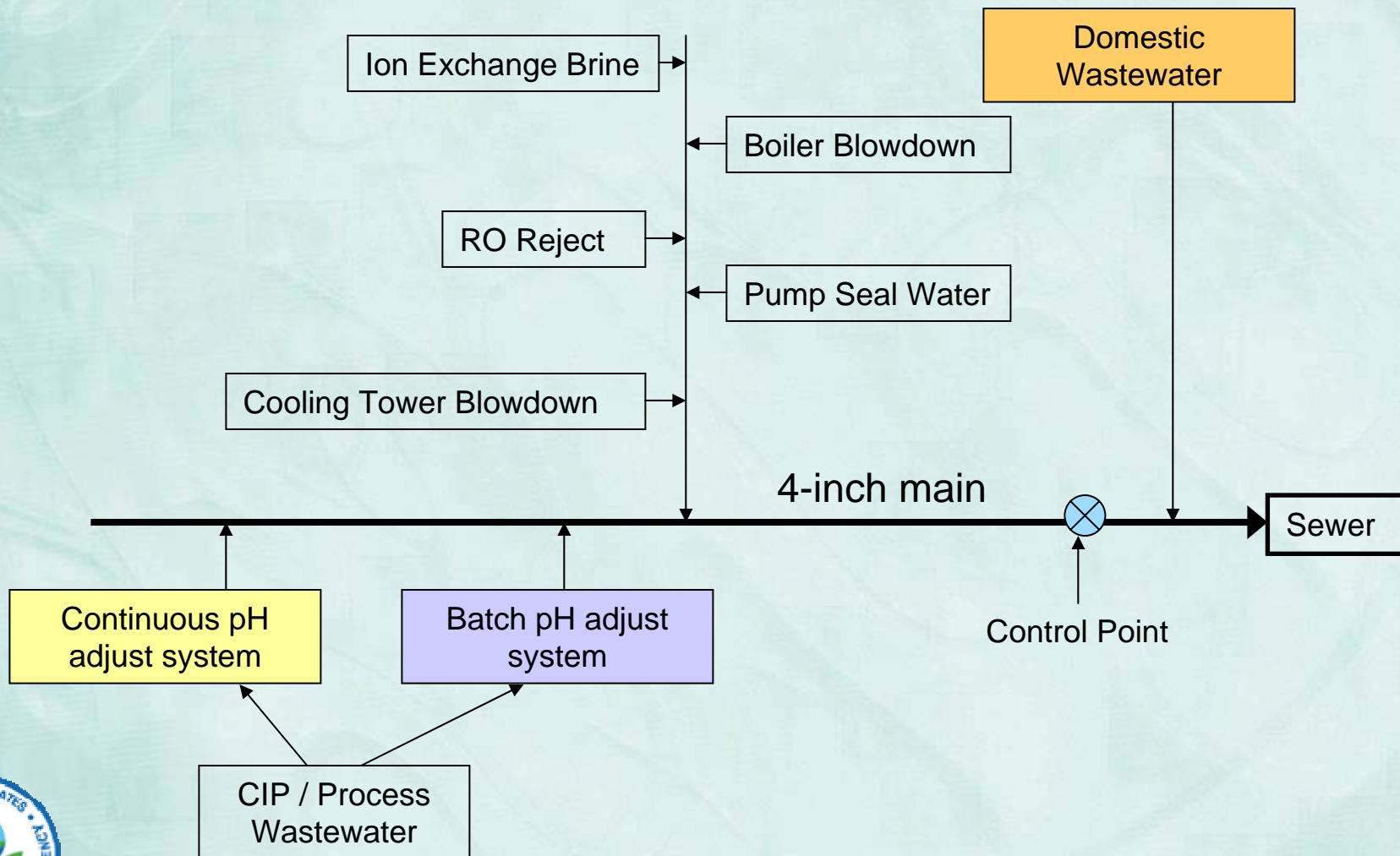


EPA Follow-up Inspection:

- May 21, 2007
- Purpose: to confirm details, gain a better understanding of All wastewater streams - discharge points, discharge locations relative to each other and check for Any variability in the waste stream makeup from morning to night



Wastewater Diagram:



EPA Follow-up Inspection:

- Conclusions:
 - The Facility could easily separate domestic wastewater from process wastewater stream.
 - pH problem is controllable and solvable with an equalization tank, at minimum.



EPA Enforcement:

- Consisted of:
 - Administrative Order (AO)
 - Administrative Penalty Order (APO)
 - Supplemental Environmental Project (SEP)



Administrative Order:

- EPA issued the AO in July 2007.
- Requirements:
 - Submit a preliminary design of a system to achieve consistent compliance with pH standards.
 - Sever the domestic wastewater line from the main wastewater line
 - EPA did not specify what the solution had to be to comply with pH standards.
 - Install and start up the proposed new system
 - Self-monitoring for one year:
 - Continuous pH monitoring
 - Submit summary of results to EPA each month



Administrative Order Conclusion:

- Installed a pH neutralization system that would treat all wastewater discharges.
- BioMarin was able to achieve consistent compliance with pH standards.
- BioMarin completed the AO requirements in August 2008.



Administrative Penalty Order:

- EPA sent a APO to BioMarin in April 2008.
- EPA resolved the penalty action in September 2008.
- EPA sent a APO because many of the violations were severe (pH as low as 1.1) and were continuous from 2004 – 2007.
- Final penalty amount: \$120K
- Estimated Cost of SEP: \$ 50K



Supplemental Environmental Project:

- EPA can consider the value of a SEP when determining the final penalty amount appropriate for a settlement.
- SEP must meet certain criteria:
 - Must be environmentally beneficial
 - Is undertaken only as settlement of an enforcement action
 - Cannot be something that the violator is otherwise legally obligated to do
 - Must possess adequate relationship, or “nexus,” to the violation
- EPA estimates the “mitigation percentage”



Supplemental Environmental Project:

- Funds a project to perform stream restoration work in Novato Creek and tributary.
- This project would not occur without this funding.
- Work being conducted by the Bay Institute will include:
 - Restoring native vegetation
 - Conducting a maintenance and monitoring program for 3 years
 - Regular status report to EPA every 6 months
 - Report with data and photographs
 - BioMarin must demonstrate an 80% survival rate of the plantings



Merck and Co. Pharmaceutical Research Facility Enforcement Case

Information Provided by
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Background:

- Merck & Co., Inc.
 - A global research-driven pharmaceutical company.
 - Merck discovers, develops, manufactures and markets vaccines and medicines.
 - A pharmaceutical research facility that is an industrial user (IU) that discharges to the Upper Gwynedd Township Publicly Owned Treatment Works (UGT POTW)

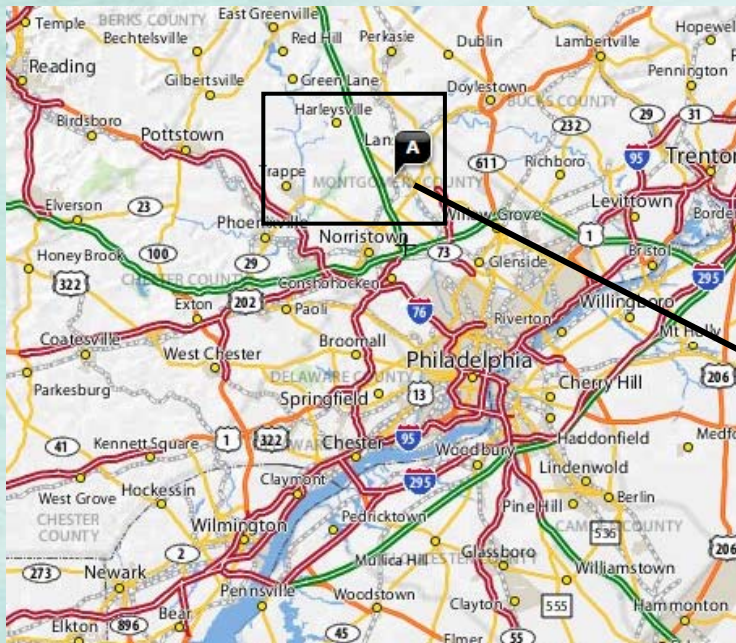


Background:

- Merck & Co., Inc.
 - Plant is located in West Point, Montgomery County and houses pharmaceutical and vaccine research as well as manufacturing products & vaccines.
 - The facility consists of approximately 400 acres, 110 buildings and employs approximately 8,500 employees.



Location: West Point, PA



Discharge Location:

- UGT POTW
 - Treated effluent is discharged into the Wissahickon Creek, a tributary of the Schuylkill River.
 - Approximately 40% of Philadelphia's drinking water is downstream of the Merck facility.



Pass Through and Interference:

- Extensive Fish Kill Observed on June 14 & 15, 2006
- City, State and EPA officials were notified
- The State department conducted an investigation at the POTW
- The City closed its Schuylkill River drinking water intake immediately
- EPA responded to the Pretreatment Concern



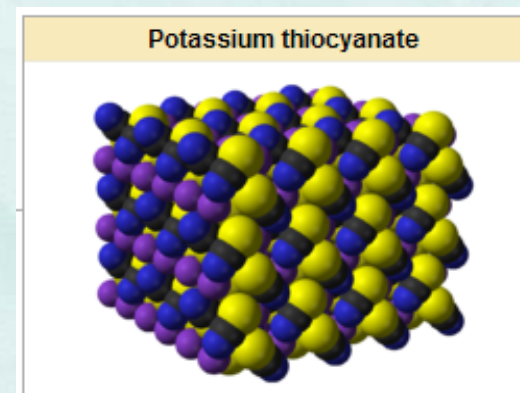
Identification of Pollutant Source:

- Began Inspections of Industrial Users
- Collection System Sampled
- Began to Track Traces of Cyanide in System
- Notification of Source of Cyanide (Merck)
- Meet with Merck to Understand Origin, Amount, and Reason for Discharge



Pollutant:

- On June 13, 2006, Merck discharged Potassium Thiocyanate “KSCN”
- Wide range of applications including use in the manufacture of industrial chemicals, pharmaceuticals and pesticides.
- Approximately 25 gallons was released into the sewer system (not in accordance with the company’s protocols)
- Synergistic combination between chlorine and cyanide forming a compound toxic to marine species.



Enforcement:

- The City, State Department and EPA signed into a Consent Decree with Merck.
- The Consent Decree requires Merck to pay:
 - \$1,575,000 in penalties (divided among parties)
 - \$10 million to put in place systems that will prevent future dangerous discharges (Injunctive Relief)
 - \$9 million for SEPs



Injunctive Relief:

- The Proposed consent decree includes interim measures to:
 - Prevent discharges without preapproval
 - Create a tracking system for waste handling
 - Create a task force to assess the system throughout the facility
 - Increase testing and assessment tools for waste stream
 - Enhanced wastewater management program
 - Chemical management accountability system for facility



SEP:

- The environmental projects are designed to improve water quality and/or protect the Wissahickon as a source of drinking water
- Merck committed to:
 - Restoration of a segment of the Wissahickon Creek
 - Creation of a wetlands on a 10 acre parcel of property adjacent to the Creek.
 - Purchase and installation of an aquatic biomonitoring system that monitors fish activity to give the City an early warning system.
 - Purchase and installation of an enhanced Automated Dissolved Oxygen Controls at the UGT POTW
 - \$4.5 Million towards the purchase of a parcel of land adjacent to the Creek that will have restricted use and open space easements in perpetuity.



Comments/Questions?

