



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY **REGION III** 1650 Arch Street Philadelphia, Pennsylvania 19103-2029

1107 0 4 2009

GENERAL NOTICE LETTER URGENT LEGAL MATTER PROMPT REPLY REQUIRED **CERTIFIED MAIL: RETURN RECEIPT REQUESTED**

Mr. Fred Hassan, Chairman and Chief Executive Officer Schering-Plough Corporation 2000 Galloping Hill Road Kenilworth, NJ 07033-0530

> Re: Millsboro TCE Groundwater Contamination Site

Dear Mr. Hassan:

Under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), commonly known as the federal "Superfund" law, the U.S. Environmental Protection Agency ("EPA") is responsible for responding to the release or threat of release of hazardous substances, pollutants, or contaminants into the environment – that is, for stopping further contamination from occurring and for cleaning up or otherwise addressing any contamination that has already occurred. EPA has documented that such a release has occurred at the Millsboro Trichloroethylene ("TCE") Groundwater Contamination Site (the "Site") located in Millsboro, Delaware. EPA has spent, or is considering spending, public funds to investigate and control releases of hazardous substances or potential releases of hazardous substances at the Site. Based on information presently available to EPA, the Agency has determined that Schering-Plough Corporation may be responsible under CERCLA for cleanup of the Site or for costs EPA has incurred in cleaning up the Site.

Explanation of Potential Liability

Under CERCLA, specifically Sections 106(a) and 107(a), 42 U.S.C. §§ 9606(a), 9607(a), potentially responsible parties ("PRPs") may be required to perform cleanup actions to protect the public health, welfare, or the environment. PRPs may also be responsible for costs incurred by EPA in cleaning up the Site, unless the PRP can show divisibility of harm or any of the statutory defenses provided by Section 107(b) of CERCLA, 42 U.S.C. § 9607(b). PRPs include current and former owners and operators of a site, as well as persons who arranged for treatment and/or disposal of any hazardous substances found at the site, and persons who accepted hazardous substances for transport and selected the site to which the hazardous substances were delivered.

Based on the information collected, EPA believes that you may be liable under Section 107(a) of CERCLA, 42 U.S.C. § 9607(a), with respect to the Millsboro TCE Groundwater Contamination Site, as an owner during the time that TCE, a hazardous substance, was disposed of at the Site.

Site Response Activities

To date, EPA, the State of Delaware, Department of Natural Resources and Environmental Control ("DNREC"), and the Town of Millsboro have taken, or are considering taking several response actions at the Site under the authority of the Superfund Program. Below is a brief description of actual response actions taken at the Site to date:

- DNREC conducted a Site investigation in 2005 to determine the probable source of elevated TCE found in the drinking water supply of the Town of Millsboro;
- Underground tanks, piping, sludge and 209 tons of contaminated soils were removed by DNREC;
- EPA conducted a removal site evaluation of groundwater analytical data from the water supply wells for the towns of Millsboro and Dagsboro and found that the TCE concentrations posed harm above the excess cancer risk level;
- DNREC has conducted and is conducting continuous sampling and monitoring of the Town of Millsboro drinking water;
- DNREC has conducted and is conducting removal of TCE from the Town of Millsboro drinking water supply;
- On July 15, 2009, EPA issued a Site Action Memorandum which provided funding for the initiation of Site removal activities to be performed under the authority of the National Contingency Plan, 40 C.F.R. Part 300; and
- On September 23, 2009, EPA proposed the Site for listing on the National Priorities List ("NPL") to initiate remedial actions to remedy the ongoing contamination. There is a 60-day public comment period offered for interested parties to participate in the proposal process.

Future Site Response Activities and Request for Participation

EPA has reason to believe that a Removal Action is necessary prior to the completion of the selection of the remedial action for implementation at the Site. The Town of Millsboro intends to install new, deeper public water supply wells free of TCE contamination. Until this installation is complete, TCE must continue to be removed from the Town of Millsboro drinking water supply and the drinking water supply must be sampled and monitored. DNREC has requested the assistance of EPA in conducting this Removal Action. At this point, EPA is requesting the participation of the PRPs, including Schering-Plough Corporation, in promptly and properly performing the Removal Action at the Site and discussing a comprehensive approach to cleanup at this Site using the Superfund Removal and Remedial Process.

Financial Concerns/Ability to Pay Settlements

EPA is aware that the financial ability of some PRPs to contribute toward the payment of response costs at a site may be substantially limited. If you believe, and can document, that your company falls within that category, please contact Ms. Racine Davis at (215) 814-5797, or have your attorney contact Ms. Cynthia Weiss at (215) 814-2659, for information on "Ability to Pay" settlements. In response, you will receive a package of information about the potential for such settlements and a form to complete with information about your company finances. You will also be asked to submit financial records, including business federal income tax returns. If EPA concludes that your company has a legitimate inability to pay the full amount of EPA's costs, EPA may offer a schedule for payment over time or a reduction in the total amount demanded from you.

Also, please note that, because EPA has a potential claim against your company, Schering-Plough Corporation must include EPA as a creditor if your company files for bankruptcy.

Information to Assist You

EPA would like to encourage communication between you, other Site PRPs, and EPA. EPA recommends that all PRPs meet to select a "steering committee" that will be responsible for representing the group's interests. Establishing a manageable group is critical to successful negotiations with EPA. If this is not possible, EPA encourages each PRP to select one person from its company or organization to represent its interests to EPA. To assist you in your efforts to communicate, please find the following attached information:

- 1. A list of names and addresses of PRPs to whom this letter is being sent.
- 2. A fact sheet that describes the Site.

Administrative Record,

Pursuant to CERCLA Section 113(k), 42 U.S.C. § 9613(k), EPA establishes an administrative record that contains documents which form the basis for EPA's decision on the selection of each response action for a site. A copy of the record for each response action selected for the Site will be available on the Internet at www.epa.gov/arweb. In addition to its availability on the Internet, the Administrative Record will be available in hard copy at specific locations, including EPA's Region III offices in Philadelphia. In an emergency removal response action performed by EPA using monies from the Hazardous Site Trust Fund (a/k/a the "Superfund"), an Administrative Record is typically established when EPA selects a response action for clean-up of a site by issuance of an Action Memo.

Resources and Information for Small Businesses

As you may be aware, on January 11, 2002, President Bush signed into law the Superfund Small Business Liability Relief and Brownfields Revitalization Act. This Act contains several exemptions and defenses to CERCLA liability, which we suggest that all parties evaluate. You may obtain a copy of the law via the Internet at http://www.epa.gov/swerosps/bf/sblrbra.htm and review EPA guidances regarding these exemptions at http://www.epa.gov/compliance/ resources/policies/cleanup/superfund.

EPA has created a number of helpful resources for small businesses. EPA has established the National Compliance Assistance Clearinghouse as well as Compliance Assistance Centers which offer various forms of resources to small businesses. You may inquire about these resources at www.epa.gov. In addition, the EPA Small Business Ombudsman may be contacted at www.epa.gov/sbo. Finally, EPA developed a fact sheet about the Small Business Regulatory Enforcement Fairness Act ("SBREFA"), which is enclosed with this letter.

PRP Response and EPA Contact

You are encouraged to contact EPA in writing within ten (10) days of the receipt of this letter to express your willingness or unwillingness to participate in future negotiations concerning this Site.

If you are already involved in discussions with State or local authorities, engaged in voluntary action or involved in a lawsuit regarding this Site, you should not interpret this letter as advising or directing you to restrict or to discontinue any such activities. You should, however, report the status of those discussions or activities in your letter to EPA. Please provide EPA with a copy of your letter to any other party involved in those discussions.

Your response to this letter should be addressed to:

Ms. Racine L. Davis (3HS62)
Compliance Officer
U.S. Environmental Protection Agency, Region III
1650 Arch Street
Philadelphia, PA 19103-2029

Please give these matters your immediate attention and consideration. If you have any questions regarding the foregoing, please contact Ms. Davis or have your attorney contact Ms. Weiss. Thank you for your prompt attention to this matter.

Sincerely,

Karen Melvin, Associate Division Director

Office of Enforcement

Hazardous Site Cleanup Division

Enclosures:

- 1) List of Potentially Responsible Parties
- 2) Site Fact Sheet
- 3) Small Business Regulatory Enforcement Fairness Act ("SBREFA") Fact Sheet

cc:

Mr. A.E. Moffitt, Sc.D. Vice President Global Safety & Environmental Affairs Intervet - Schering-Plough Animal Health 56 Livingston Avenue Roseland, New Jersey 07068-1733

Mr. Robert C. Asreen, Jr., DNREC-SIRB 391 Lukens Drive New Castle, DE 19720

Racine Davis (3HS62) Christian Matta (3HS23) Michael Towle (3HS31) Cynthia Weiss (3RC42) Jim Williams (3HS62)

ENCLOSURE 1

Millsboro TCE Groundwater Contamination Site List of Potentially Responsible Parties

- Mr. Fred Hassan
 Chairman and Chief Executive Officer
 Schering-Plough Corporation
 2000 Galloping Hill Road
 Kenilworth, NJ 07033-0530
- Mr. Raul E. Kohan
 President
 Intervet Schering-Plough Animal Health Corporation
 Global Supply Chain
 Union, NJ 07083-7143
- 3. Mr. Hiram Dennis Lasher P.O. Box 345
 Millsboro, DE 19966
- 4. Dr. Hiram N. Lasher, DVM 28466 S. Dupont Hwy. P.O. Box 1727 Millsboro, DE 19966
- Mr. Timothy Wright
 President
 Mallinckrodt Veterinary, Inc.
 675 McDonnell Boulevard
 Hazelwood, Missouri 63042

ENCLOSURE 2



Department of Natural Resources and Environmental Control (DNREC) Site Investigation and Restoration Branch (SIRB) Site Fact Sheet for Millsboro Public Well TCE Site Millsboro, Delaware (DE-1361)

Site Location and Description: The Millsboro Public Well TCE Site is located approximately between S. DuPont Highway and State Street in Millsboro, Sussex County, Delaware. The Site is approximately 1500 feet long and 300 feet wide and consists of a source area at the intersection of Wharton Street and S. DuPont Highway; a recovery area, located at Town of Millsboro's Wellfield on West Church Street, and the impacted groundwater under the properties in between.

Site Operation History: Poultry vaccine manufacturing operations began on the source area property in 1952 with the establishment of Delaware Poultry Laboratories, Inc. Sterling Drug Company purchased Delaware Poultry Laboratories sometime in the 1960s and operated the property as Sterwin Laboratories until 1984, when International Minerals and Chemical (IMC) purchased Sterwin Laboratories from Sterling Drug. Between 1984 and 1997, the operating company name changed to IMCERA, Pitman-Moore, and then to Mallinckrodt Veterinary, Inc. without a change of ownership.

On June 30, 1997, Schering-Plough Corporation (Schering Plough) acquired the animal health business including the property of Mallinckrodt, Inc. and Mallinckrodt Veterinary, Inc. through a stock purchase agreement. Schering Plough conducted poultry vaccine manufacturing operations on the TCE Site until August 1999.

Schering Plough had the building demolished in December 2000 and then sold the property to Hiram Dennis Lasher on June 29, 2001. Since that time Hiram Dennis Lasher has owned the property but apparently has not operated any business on the property.

Environmental Investigations and Actions: Trichloroethylene (TCE) was detected by the Office of Drinking Water (ODW) at a concentration that exceeded the Maximum Contaminant Level (MCL) for that compound of 5 parts per billion (ppb) in a routine water sample from the Boys & Girls Club located in Dagsboro, Delaware on October 19, 2005. Dagsboro water is supplied by the Town of Millsboro (TOM), Delaware. The public water supply system for Millsboro and Dagsboro was taken offline after the discovery of TCE. The ODW issued a public notice on October 24, 2005 restricting water use and supplied water to residents by bottles and tankers. In addition, domestic wells were sampled by the ODW on November 2, 2005. Interim response actions (IRAs) were immediately taken by DNREC and the TOM to outfit the town public water supply wells with granulated activated carbon (GAC) to treat extracted groundwater at the wellhead before distribution. The TOM also instituted a public water supply well sampling and chemical analysis program to monitor for TCE and other volatile organic compounds (VOCs) and to assess the effectiveness of the GAC treatment before distribution. Public notices were lifted from Millsboro and Dagsboro on November 23, 2005 and December 2, 2005, respectively.

Concurrently, DNREC initiated an aggressive and comprehensive investigation between December 2005 and April 2006 to identify the extent and source (i.e., origin) of TCE contamination in groundwater. Approximately, 100 locations were sampled via direct push methods on 27 tax parcels to the east, west, and south of the Millsboro Water Treatment Plant. Approximately 300 groundwater samples were collected from depths ranging from 12 ft. below ground surface (bgs) to 90 ft. bgs. Samples were screened in the DNREC-SIRB laboratory in New Castle for VOCs including TCE and the associated degradation products. After review and synthesis of the preliminary investigation results, the source of the TCE in groundwater was identified at West DuPont Highway at the intersection of Wharton Street in Millsboro. The source property was the location of a poultry vaccine manufacturing operation between 1952 and August 1999. 209 tons of contaminated soil as well as underground septic tanks and piping have been addressed by DNREC under an interim source area removal action in 2006. In January 2008, DNREC collected

additional soil and groundwater samples on the source property. During May and June 2008, 17 wells were installed and sampled by DNREC to monitor the groundwater contaminant plume.

Several assessments have been conducted on the source area property in the past, including: Phase I & Phase II Environmental Site Assessment, Mallinckrodt Veterinary, Inc. (Metcalf & Eddy, 1998), Hydrologic Investigation (Environmental Resources Management, 1998), Report on Former Diesel Underground Storage Tank Removal and Well Abandonment for the Former Mallinckrodt Facility-Millsboro, Delaware (ERM 2001). A "No Further Action" letter was issued to Schering Plough by the DNREC-TMB for the naphthalene plume on March 19, 2001.

Groundwater sampling and monitoring: Groundwater sampling and monitoring has been conducted by the Town of Millsboro on a weekly basis for the two impacted supply wells. During May and June 2008, DNREC has installed and sampled 17 groundwater wells to monitoring the contaminant plume. The groundwater monitoring wells, installed as multi well clusters, are screened at 10 foot intervals ranging from 15 to 25 feet below ground surface (bgs) to 90-100 feet bgs throughout the contaminant plume.

Geology and hydrogeology: The geology of the area has been characterized by soil borings spread across the area of the plume. The borings were drilled to depths ranging from 12 feet below ground surface (bgs) to 100 feet bgs. Based on the data collected from the monitoring wells, the groundwater flow direction is towards the northeast. The unconfined Columbia aquifer is comprised of the sands of the Beaverdam Formation. The sands of the Beaverdam fine upward from medium and coarse grained sand at the base to fine grained sand, silts clays at top. Millsboro's PW-1 and PW-2 are screened between 70 and 90 feet bgs in the unconfined aquifer. The predominately clays and silts with discontinuous lenses of fine to coarse grained sand of the Bethany Formation underlie the Beaverdam Formation and comprise the confined Pocomoke aquifer. The Pocomoke aquifer is underlain by the sands, with minor beds of silts and clays, of the Cat Hill Formation. which comprise the confined Manokin aquifer. Millsboro's PW-3, PW-4 and PW-5 are screened between 200 and 250 ft. in the Cat Hill Formation.

Contaminants of Potential Concern (COPC): Environmental sampling indicates that trichloroethylene (TCE) is the primary COPC in groundwater throughout the site and in the soil at the source area.

Current Status: The Town of Millsboro is currently filtering groundwater through activated carbon to meet drinking water standards. DNREC has performed a removal action of soil, tanks and piping at the source area. All expenditures thus far have been from the HSCA Fund. DNREC has sent notice letters to the Potentially Responsible Parties (PRPs). DNREC has installed and sampled 17 groundwater monitoring wells. DNREC is planning to initiate a In Situ Chemical Oxidation Pilot Study on September 29, 2008.

Cleanup Stage: A final plan of remedial action for the Site was approved by DNREC on January 2, 2008. DNREC is planning to initiate a In Situ Chemical Oxidation Pilot Study as part of the pre remedial design to treat both the soil and groundwater at the source area. The pilot study is expected to start on September 29, 2008 and run through July, 2009.

Funding: To date, DNREC has spent over \$1.5 million of Hazardous Substance Cleanup Act (HSCA) fund money to conduct investigations and perform remedial actions at the Site as well as treatment and sampling of the groundwater from the impacted supply wells

Contact: For Further Information contact Robert Newsome at 302-395-2600 or by e-mail at Robert.Newsome@state.de.us.

Last Updated: September 25, 2008 - RCA



Office of Enforcement and Compliance Assurance

INFORMATION SHEET

U. S. EPA Small Business Resources

f you own a small business, the United States Environmental Protection Agency (EPA) offers a variety of compliance assistance resources such as workshops, training sessions, hotlines, websites, and guides to assist you in complying with federal and state environmental laws. These resources can help you understand your environmental obligations, improve compliance, and find costeffective ways to comply through the use of pollution prevention and other innovative technologies.

Compliance Assistance Centers

(www.assistancecenters.net)

In partnership with industry, universities, and other federal and state agencies, EPA has established Compliance Assistance Centers that provide information targeted to industries with many small businesses.

Aariculture

(www.epa.gov/agriculture or 1-888-663-2155)

Automotive Recycling Industry (www.ecarcenter.org)

Automotive Service and Repair (www.ccar-greenlink.org or 1-888-GRN-LINK)

Chemical Industry (www.chemalliance.org)

Construction Industry (www.cicacenter.org or 1-734-995-4911)

Education

(www.campuserc.org)

Healthcare Industry

(www.hercenter.org or 1-734-995-4911)

Metal Finishing

(www.nmfrc.org or 1-734-995-4911)

Paints and Coatings

(www.paintcenter.org or 1-734-995-4911)

Printed Wiring Board Manufacturing

(www.pwbrc.org or 1-734-995-4911)

Printing

(www.pneac.org. or 1-888-USPNEAC)

Transportation Industry

(www.transource.org)

Tribal Governments and Indian Country (www.epa.gov/tribal/compliance or 202–564-2516)

US Border Environmental Issues

(www.bordercenter.org or 1-734-995-4911)

The Centers also provide State Resource Locators (www.envcap.org/statetools/index.cfm) for a wide range of topics to help you find important environmental compliance information specific to your state.

EPA Websites

EPA has several Internet sites that provide useful compliance assistance information and materials for small businesses. If you don't have access to the Internet at your business, many public libraries provide access to the Internet at minimal or no cost.

EPA's Home Page www.epa.gov

Small Business Gateway

www.epa.gov/smallbusiness

Compliance Assistance Home Page

www.epa.gov/compliance/assistance

Office of Enforcement and Compliance Assurance www.epa.gov/compliance

Voluntary Partnership Programs www.epa.gov/partners

Office of Enforcement and Compliance Assurance: http://www.epa.gov/compliance

U.S. EPA SMALL BUSINESS RESOURCES

Hotlines, Helplines & Clearinghouses

(www.epa.gov/epahome/hotline.htm)

EPA sponsors many free hotlines and clearinghouses that provide convenient assistance regarding environmental requirements. A few examples are listed below:

Clean Air Technology Center

(www.epa.gov/ttn/catc or 1-919-541-0800)

Emergency Planning and Community Right-To-Know Act (www.epa.gov/superfund/resources/infocenter/epcra.htm or 1-800-424-9346)

EPA's Small Business Ombudsman Hotline provides regulatory and technical assistance information. (www.epa.gov/sbo or 1-800-368-5888)

The National Environmental Compliance Assistance Clearinghouse provides quick access to compliance assistance tools, contacts, and planned activities from the U.S. EPA, states, and other compliance assistance providers (www.epa.gov/clearinghouse)

National Response Center to report oil and hazardous substance spills. (www.nrc.uscq.mil or 1-800-424-8802)

Pollution Prevention Information Clearinghouse (www.epa.gov/opptintr/ppic or 1-202-566-0799)

Safe Drinking Water Hotline

(www.epa.gov/safewater/hotline/index.html or 1-800-426-4791)

Stratospheric Ozone Refrigerants Information (www.epa.gov/ozone or 1-800-296-1996)

Toxics Assistance Information Service also includes asbestos inquiries.

(1-202-554-1404)

Wetlands Helpline

(www.epa.gov/owow/wetlands/wetline.html or 1-800-832-7828)

State Agencies

Many state agencies have established compliance assistance programs that provide on-site and other types of assistance. Contact your local state environmental agency for more information or the following two resources:

EPA's Small Business Ombudsman (www.epa.gov/sbo or 1-800-368-5888)

Small Business Environmental Homepage (www.smallbiz-enviroweb.org or 1-724-452-4722)

Compliance Incentives

EPA provides incentives for environmental compliance. By participating in compliance assistance programs or voluntarily disclosing and promptly correcting violations before an enforcement action has been initiated.

businesses may be eligible for penalty waivers or reductions. EPA has two policies that potentially apply to small businesses:

The Small Business Compliance Policy

(www.epa.gov/compliance/incentives/smallbusiness)

Audit Policy

(www.epa.gov/compliance/incentives/auditing)

Commenting on Federal Enforcement Actions and Compliance Activities

The Small Business Regulatory Enforcement Fairness Act (SBREFA) established an SBA Ombudsman and 10 Regional Fairness Boards to receive comments from small businesses about federal agency enforcement actions. If you believe that you fall within the Small Business Administration's definition of a small business (based on your North American Industry Classification System (NAICS) designation, number of employees, or annual receipts, defined at 13 C.F.R. 121.201; in most cases, this means a business with 500 or fewer employees), and wish to comment on federal enforcement and compliance activities, call the SBREFA Ombudsman's toll-free number at 1-888-REG-FAIR (1-888-734-3247).

Every small business that is the subject of an enforcement or compliance action is entitled to comment on the Agency's actions without fear of retaliation. EPA employees are prohibited from using enforcement or any other means of retaliation against any member of the regulated community in response to comments made under SBREFA.

Your Duty to Comply

If you receive compliance assistance or submit comments to the SBREFA Ombudsman or Regional Fairness Boards, you still have the duty to comply with the law, including providing timely responses to EPA information requests. administrative or civil complaints, other enforcement actions or communications. The assistance information and comment processes do not give you any new rights or defenses in any enforcement action. These processes also do not affect EPA's obligation to protect public health or the environment under any of the environmental statutes it enforces, including the right to take emergency remedial or emergency response actions when appropriate. Those decisions will be based on the facts in each situation. The SBREFA Ómbudsman and Fairness Boards do not participate in resolving EPA's enforcement actions. Also, remember that to preserve your rights, you need to comply with all rules governing the enforcement process.

EPA is disseminating this information to you without making a determination that your business or organization is a small business as defined by Section 222 of the Small Business Regulatory Enforcement Fairness Act or related provisions.