Project XL

Environmental Excellence and Leadership

Annual Progress Report

PARTNERS EXCELLING IN ENVIRONMENTAL LEADERSHIP

March 1, 2001

Introduction

As part of former President Clinton's initiatives for reinventing government, Project eXcellence and Leadership (XL) was introduced in 1995. This project afforded a novel means of achieving environmental progress outside of the constraints of existing regulations. In 1996, Merck kicked off a project to deliver superior environmental protection while allowing flexible operation at its pharmaceutical manufacturing facility in Elkton, Virginia. Merck, along with representatives from the Environmental Protection Agency, the Virginia Department of Environmental Quality, the National Park Service, and the local community, developed a simplified air permit for the Stonewall Plant that reduced total air emissions of criteria pollutants while allowing the plant flexibility to make changes and additions to its manufacturing processes without prior environmental regulatory approval. This is the first Annual Progress Report, issued as specified in Merck's air permit, to inform the project stakeholders and other interested parties of Merck's actual emissions and emissions reductions as a result of Project XL.

Merck & Co., Inc. is a worldwide research-intensive health products company that discovers, develops, manufactures, and markets human and animal health products. Merck's Stonewall Plant, located near Elkton, Virginia, was established in 1941. Merck chose the Elkton area for the advantages of easy access to transportation routes, access to water, room for expansion, an adequate labor pool, and no other industrial competition. Once Merck purchased the property, company officials impressed the residents of Elkton with their commitment to the community. They stressed the fact that Merck would be a permanent industry in Rockingham County. Local labor was employed on the building of the site, as well as some 300 plant jobs once manufacturing began.

The Shenandoah River bordering the plant site

The Stonewall Plant was named in recognition of the historical Stonewall district of Rockingham County. Eight and one half months after the groundbreaking ceremony, the Stonewall Plant was put into operation. The first manufacturing of ingredients for thiamine began on December 17,

1941, only ten days after the bombing of Pearl Harbor. The Stonewall Plant foreshadowed an important national need for drugs and vitamins and provided employment and an important new community resource for Virginia residents.

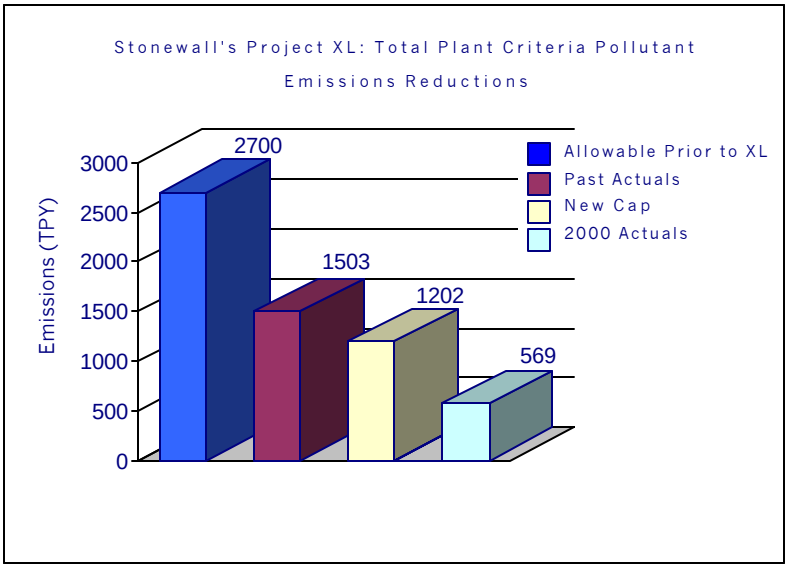
Today, Stonewall is the only domestic Merck Manufacturing Division facility that accommodates bulk chemical manufacturing and pharmaceutical formulation and packaging operations for human pharmaceuticals. Currently the plant employs about 900 people in a range of pharmaceutical manufacturing activities such as fermentation, solvent extraction, organic synthesis, finishing and packaging operations. The plant's products include broad spectrum antibiotics, antiparasitic drugs for human and animal health, a cholesterol lowering drug, a new antifungal drug, and medicines for the treatment of Parkinson's disease and the human immunodeficiency virus.

Project Background

Historically, bringing a new product to the site required that air permits be issued before construction of facilities necessary to manufacture the product. This requirement had the potential to significantly lengthen the time it took to introduce a new drug to the marketplace. The flexibility afforded by Project XL not only affords Merck a competitive edge in bringing new drugs to the market, but it also ensures that consumers will be provided with the pharmaceutical products that they need in less time. Even more importantly, the Stonewall Plant is located near the Shenandoah National Park, a delicate natural ecosystem which is provided with special protection under the Clean Air Act. The plant's proximity to this important natural resource highlights the need for serious consideration of opportunities that provide better protection of the environment, especially as it applies to air quality.

Prior to Project XL, Merck Stonewall Plant's allowable total criteria pollutant emissions were about 2700 tons per year(TPY). Under Project XL, Merck agreed to set the total criteria pollutant emissions cap at 1503 TPY (the actual average emissions level for 1992-1993). As part of the negotiation process, Merck agreed to further reduce the criteria pollutant cap to 1202 TPY, providing a superior environmental benefit in the form of 300 TPY of permanent emissions reductions. In addition, specific limits were established for those pollutants of particular concern for health and the local environment: SO_2, NO_x, and PM10. In order to gain the operating flexibility under project XL, Merck made a voluntary commitment to accept the new permit; this required reducing pollutant emissions significantly by converting its existing powerhouse from coal burning to cleaner burning natural gas. This conversion decreased criteria pollutant emissions by over 900 TPY. Actual criteria pollutant emissions for the 12 month period ending December 31, 2000 were 569 TPY. This total reflects the impact of the burning of natural gas for about half of the year once the powerhouse was completed. Most of these emission reductions were in $S0_2$ and NO_x which have the greatest potential for adverse impacts on local air quality such as visibility, ozone formation, and acid rain. In addition, emissions of hydrogen chloride (HCl) and hydrogen fluoride (HF), two hazardous air pollutants,

will be reduced by about 40 tons and 5 TPY respectively. The impact of Project XL on the Stonewall Plant's emissions is shown below.



Project Timeline and Status

The Project XL PSD (Prevention of Significant Deterioration) permit became effective on February 10, 1998. The conversion of the powerhouse commenced on July 25, 1998 and was completed on July 12, 2000. Burning of the new fuels (natural gas/oil) in order to demonstrate the new equipment actually began in May, 2000. The performance tests to confirm actual emissions from each of the new boilers were conducted from September 28-29, 2000 and from October 2-6, 2000. These performance tests verified the magnitude of emissions reductions achieved; actual emissions reductions for 2000 are detailed in Table 1.

TABLE 1: Summary of Criteria Pollutant Reductions (tons) achieved from May through December, 2000 due to conversion of the Merck Stonewall Plant Powerhouse

POLLUTANT	BEFORE PH CONVERSION (COAL)	AFTER PH CONVERSION (NATURAL GAS/OIL)	TOTAL REDUCTION
SO_2	302.5	1.7	300.8
NO_x	147.5	12.3	135.2
PM_{10}	20.7	1.1	19.6
Total Criteria Pollutants	483.1	22.0	**461.1 tons**

(incl. CO & VOC)

Note: The calculated criteria pollutant emissions reductions illustrated in Table 1 represent reductions achieved by burning natural gas as compared to those emissions that would have occurred using an equivalent energy input of coal. The criteria pollutant emissions factors used for coal consumption were the same as those used for establishing the Project XL emission baseline. The criteria pollutant emissions for the new boilers (natural gas and fuel oil) are based on the performance test for the appropriate steam load used during that period.

Pursuant to the phase-in provisions of the PSD permit, the new emissions caps, monitoring, reporting and recordkeeping requirements, and regulatory relief were to become effective twelve months after the conversion of the powerhouse was completed or upon written notification by Merck, whichever was sooner. By November 9, 2000, the emissions reduction achieved from burning natural gas instead of coal had reduced the 12-month rolling total of pollutant emissions (sum of previous twelve month's emissions) below the new permit caps. The stakeholders were notified and Merck began operating under all of the terms and conditions of the new PSD permit.

Gas boiler being positioned for installation in the powerhouse

Pollution Prevention

Pollution prevention efforts have been an integral part of Merck's mission to provide society with superior quality pharmaceutical products and services. These efforts traditionally have been accomplished informally as a natural by-product of its ongoing efforts to improve environmental and safety performance, process yields and competitiveness in the marketplace.

Historically, pollution prevention accomplishments have come directly from process yield improvement projects. These projects focused on improving process efficiency, reducing waste and lowering costs. More recently, efforts have focused on reducing toxic chemical emissions and maintaining the capacity of on and off site solid waste and wastewater treatment facilities. Increasingly, pollution prevention efforts are emphasized in the process design phase at Merck's research and development laboratories, prior to introducing a new process to the plant.

Most of the ideas for process improvements come from chemical operators, production supervisors and on site technical support staff. These ideas may be conveyed informally on the factory floor, during routine brainstorming sessions, or during regular safety, good manufacturing practices and management dialogue meetings. These ideas are usually recorded in meeting minutes and screened for economic and technical viability. Viable ideas are documented and implemented through Process Changes, Work Orders or both. Process Changes that result in significant financial savings to the plant are further documented as Productivity Targets.

Stonewall's solvent recovery facility is integral to the site's pollution prevention effort. This facility receives spent solvents from the production areas, processes these solvents to purify them, then returns the clean solvents to the production areas for reuse. The powerhouse conversion from coal to natural gas, one of the largest pollution prevention projects in the plant's history, provided not only a significant instantaneous emissions reduction, but a long term guarantee that the previously allowable site emissions will be permanently reduced by about 1500 TPY.

Emissions Summary

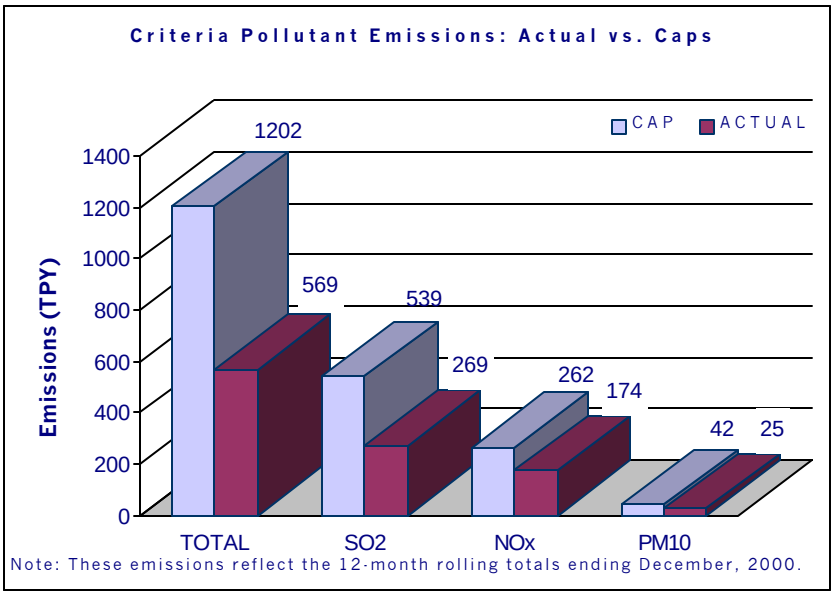
Sulfur dioxide (SO_2) emissions at Merck's Stonewall plant result primarily from the combustion of fossil fuels that contain sulfur compounds. SO_2 can damage plant life, scatter light to reduce visibility, contribute to acid rain that can damage buildings and equipment, and cause respiratory tract irritation. Total SO_2 emissions prevented in 2000 by the powerhouse conversion were 300.8 tons.

Nitrogen Oxides (NO_x) are also formed during combustion. NO_x can be emitted from both the nitrogen found in the fuel itself and from the formation of NOx in the thermal oxidation process of combustion. NOx can cause adverse health effects, contribute to hazy visibility and form acid rain; but the primary environmental concern is that NO_x can react with volatile organic compounds in the presence of sunlight to create ground level ozone(O_3). Ozone in the upper atmosphere is beneficial since it protects the earth from ultraviolet light; however, ground level ozone damages vegetation and materials including rubber, and can have adverse affects on pulmonary function in humans. Since locally the formation of ozone is limited by the amount of NO_x present, the NO_x reductions achieved by this project are of particular importance. Total NOx emissions prevented in 2000 by the powerhouse conversion were 135.2 tons.

Volatile Organic Compound (VOC) emissions, resulting mainly from the use of solvents in the various pharmaceutical manufacturing processes, can react with NO_x to form ground level ozone. Total VOC emissions prevented in 2000 by the powerhouse conversion were 0.4 tons.

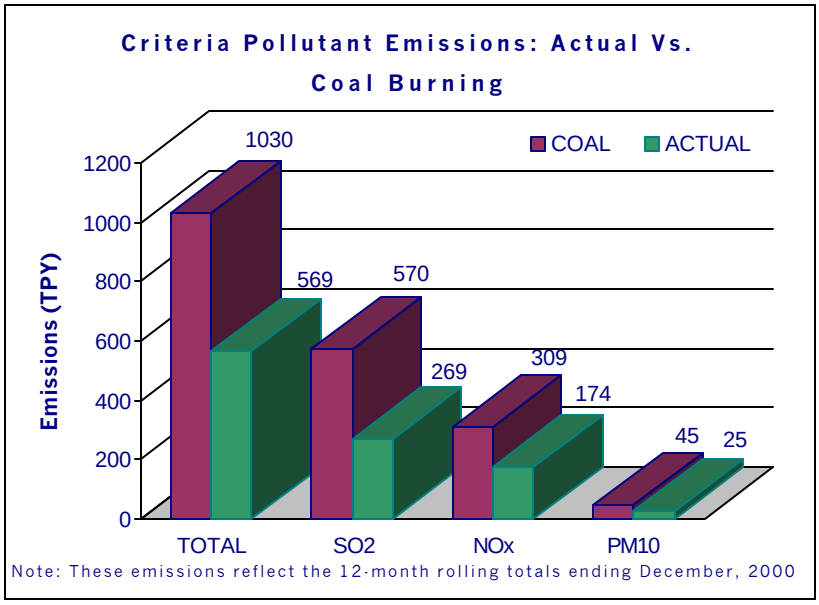
This is a small number because the powerhouse is a relatively minor source of VOC emissions for the site.

Carbon Monoxide (CO), another byproduct of combustion, can cause serious adverse health effects. Total CO emissions prevented in 2000 by the powerhouse conversion were 5.1 tons. Particulate Matter10 (PM10) are solids with a diameter less than or equal to ten microns. These small particles can irritate the human respiratory system, impair visibility, and contribute to acidic dry deposition. Total PM10 emissions prevented in 2000 by the powerhouse conversion



were 19.6 tons. The graph below shows the total emissions for 2000, along with the emissions caps specified in the PSD permit.

If the powerhouse conversion had not occurred and coal continued to be burned in the old boilers, emissions would have been much higher, as illustrated in the graph below. Note that in both the previous graph and the one below, the twelve month rolling totals include over half a year of coal burning; therefore future emissions are expected to be even lower.



Future

As an ongoing benefit of Project XL, the powerhouse conversion will provide substantial cumulative criteria pollutant emissions reductions for years to come. As previously stated, three hundred tons of air pollutant emissions have been permanently retired to operate under the new emissions cap of 1202 TPY of total criteria air pollutant emissions. While 300 TPY of emissions reduction are guaranteed, Merck is currently operating well below the permitted emissions limits We believe that the incentives in the permit to keep our criteria pollutant emissions low will help ensure that this project will deliver superior environmental benefits for years to come.

MERCK

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