

US EPA ARCHIVE DOCUMENT

February 28, 2013



Re: Project XL (eXcellence and Leadership)
Annual Progress Report for Operations in 2012

Dear Project XL Stakeholders and Other Interested Parties:

In accordance with the provisions of its Project XL Permit, the Merck Stonewall Plant is pleased to provide its tenth Annual Progress Report for operations in 2012. This report provides information on our performance under the terms of the XL permit and other pertinent environmental topics.

We thank each of you for your continuing interest in our Project XL and look forward to working with our stakeholders to continue its success in bringing superior environmental benefits to our community.

Sincerely,

A handwritten signature in black ink that reads 'John McCloskey'. The signature is fluid and cursive, with the first name 'John' being particularly prominent.

John McCloskey
Environmental Services Manager



Project XL Annual Progress Report

Introduction

As part of former President Clinton's initiatives for reinventing government, Project XL (the eXcellence in Leadership Program) was introduced in 1995. This program afforded a novel means of achieving environmental progress outside of the constraints of existing regulations.

In 1996, Merck began 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 13th 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.

Project Background

Historically, bringing a new product to the site required that air permits be issued before construction of the facilities necessary to manufacture the product. This requirement had the potential to significantly increase the time it took to introduce a new drug to the marketplace.

The flexibility provided 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 that 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.

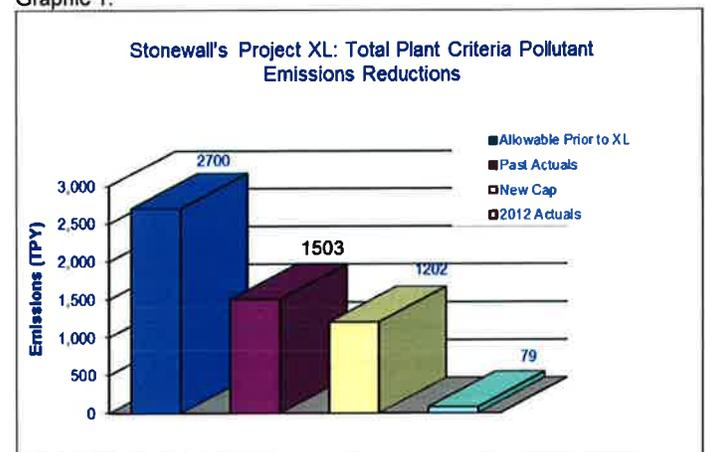
Prior to Project XL, Merck Stonewall Plant's allowable total criteria pollutant emissions were about 2,700 tons per year (TPY). Under Project XL, Merck agreed to set the total criteria pollutant emissions cap at 1,503 TPY initially (the actual average emissions level for 1992-1993).

As part of the negotiation process, Merck agreed to further reduce the criteria pollutant cap to 1,202 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 to health and the local environment: SO₂, 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 immediately by more than 900 TPY.

Actual total criteria pollutant emissions for the 12-month period ending December 31, 2012 were 79 TPY. The impact of Project XL on the Stonewall Plant's emissions is displayed on Graphic 1:

Graphic 1:



TPY = Tons per Year

Emissions Summary

The Project XL PSD (Prevention of Significant Deterioration) permit became effective on February 10, 1998. The conversion of the powerhouse began on July 25, 1998 and was completed on July 12, 2000. Comparison of the actual emissions for 2012 versus those prior to the powerhouse conversion are detailed in **Table 1**.

Table 1:

| Summary of Criteria Pollutant Reductions (tons) achieved at the Merck Stonewall Plant Powerhouse from January through December 2012 due to conversion from coal to natural gas. | | | |
|--|--|--|------------------------|
| POLLUTANT | BEFORE PH CONVERSION (COAL) | AFTER PH CONVERSION (NATURAL GAS/OIL) | TOTAL REDUCTION |
| SO ₂ | 491.8 | 0.3 | 491.5 |
| NO _x | 231.4 | 16.8 | 214.6 |
| PM ₁₀ | 33.6 | 1.4 | 32.2 |
| Total Criteria Pollutants (incl. CO & VOC) | 776.4 | 23.7 | 752.6 |

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.

Sulfur dioxide (SO₂) emissions at Merck's Stonewall plant result primarily from the combustion of fossil fuels that contain sulfur compounds. Total SO₂ emissions prevented in 2012 by using natural gas were 491.5 tons.

Nitrogen oxides (NO_x) are also formed during combustion. Typically NO₂ forms quickly from emissions from cars, trucks and buses, power plants, and off-road equipment. NO_x can be emitted from both the nitrogen found in the fuel itself and from the formation of NO_x in the thermal oxidation process of combustion. Total NO_x emissions prevented in 2012 by the powerhouse conversion were 214.6 tons.

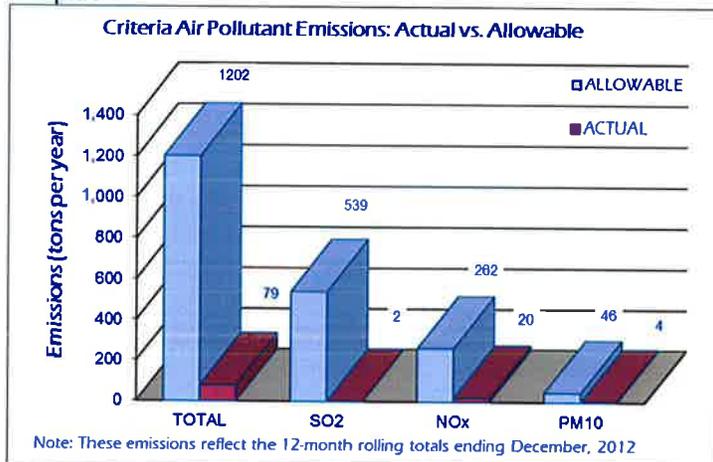
Volatile Organic Compounds (VOC) emissions, resulting mainly from the use of solvent in the various pharmaceutical manufacturing processes, can react with available NO_x to form ground level ozone. Total VOC emissions prevented in 2012 by the powerhouse conversion were 0.69 tons. This is a small number since the powerhouse is a relatively minor source of VOC emission for the site.

Carbon monoxide (CO) is another byproduct of combustion. Total CO emissions prevented in 2012 by this conversion were 13.6 tons.

"Particulate matter," also known as particle pollution or PM, is a complex mixture of extremely small particles and liquid droplets. Particulate Matter 10 (PM₁₀) are particles with a diameter less than or equal to ten microns. These particles can be directly emitted from combustion sources. Total PM₁₀ emissions prevented in 2012 by the powerhouse conversion were 32.2 tons.

The following graph shows the total emissions for 2012 as compared to the site's emissions caps.

Graphic 2



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 is the only domestic Merck Manufacturing facility that accommodates bulk chemical manufacturing, pharmaceutical formulation and packaging, and vaccine manufacturing operations for human pharmaceuticals.