Project XL For Facilities
Final Project Agreement Application

Merck & Co., Inc.
Stonewall Plant
Elkton, Virginia

Introduction

Merck & Co., Inc. (Merck) is a worldwide research-intensive health products company that discovers, develops, manufactures, and markets human and animal health products. Worldwide, Merck employs about 35,000 people at research and manufacturing facilities. Merck strives to eradicate disease, alleviate pain, and improve world health through the discovery and manufacture of innovative pharmaceutical products.

Merck's Stonewall Plant, near Elkton (Virginia), was established in 1941. The plant is located within 10 kilometers of a Class I area (Shenandoah National Park). Currently, the plant employs about 700 people in a range of pharmaceutical manufacturing activities, such as fermentation, solvent extraction, organic chemical synthesis, and finishing operations. Stonewall's products include broad spectrum antibiotics, anti-parasitic drugs for human and animal health, a cholesterol reducing drug, and a drug for the treatment of Parkinson's disease. In 1996, production of a new AIDS drug is expected to begin.

Merck's Need For Flexibility

Speed to market for new products, and new claims for existing products, is at the heart of the company's need to have flexible manufacturing facilities that can make a broad range of products in the same equipment, using a wide array of raw materials and solvents. Thus the ability of Merck's manufacturing plants to respond to rapidly changing market conditions and product demands is critical to Merck's ability to stay competitive in a worldwide pharmaceutical industry.

In addition to needing flexibility to introduce new products, Merck's business culture, which encourages continuous evaluation of existing products for yield and business improvements, creates frequent manufacturing changes in existing products. For example, the Stonewall Plant has a Technical Operations Group of 75 scientists, engineers, and technicians that set annual productivity goals for most products at the plant. Specific process improvement goals are defined and the plant uses its program to achieve process goals that often reduce emissions per unit of product produced. Thus, Merck facilities are likely to modify environmental permits frequently after a product is first permitted.

Significant procedural delays in modifying environmental permits would place Merck at a competitive disadvantage. It is essential that flexible manufacturing plants have flexible environmental permits.

The Current and Future Regulatory Environment At Stonewall

Due to its proximity to a Class I area, the Stonewall Plant is significantly affected by the Prevention of Significant Deterioration (PSD) regulations. The PSD regulations require Stonewall to evaluate the net emission increase of physical or operational changes by comparing potential emissions after the change to actual emissions before the change. Given the ever-changing production mix at pharmaceutical plants and the inappropriateness of conventional "potential to emit" calculations for batch manufacturing operations, the existing actual to potential comparison leads to cases where even emission decreases can trigger PSD evaluation. Since the PSD evaluation would result in such disproportionate resource demands on both the facility and reviewing agency, the Stonewall Plant would be discouraged from making process changes, including pollution prevention projects that would decrease actual emissions, if the actual to potential comparison would trigger PSD.

With respect to present and future regulations, Stonewall is subject to state BACT requirements, will need a Title V operating permit, and is likely to be subject to the hazardous air pollutant (HAP) modification rule (Section 112(g) of the 1990 Clean Air Act), the maximum achievable control technology (MACT) standards for pharmaceutical production processes and the MACT standard for industrial boilers. In addition, the plant is also subject to the RCRA Air Emission Standards.

Taken together, the interplay of the PSD regulations, the Title V operating permit rule, the MACT standards, and the HAP modification rule will create layers of regulatory requirements that are likely to significantly reduce Stonewall's flexibility in the future. Therefore, Merck is interested in developing an alternative permitting strategy that produces greater environmental benefit than the sum of the existing, and future potential regulations, while giving the plant flexibility to respond quickly to market demands and to provide long term growth opportunities for the Stonewall Plant.

Merck's XL Proposal

The Stonewall Plant currently emits over 1500 tons per year of regulated pollutants. The plant's primary pollutants are SO_2, NO_X, VOC, and HCL. The Merck Stonewall Plant will achieve an 85 percent (1,213,000 lb.) voluntary reduction of total SARA releases by

the end of 1995 versus the baseline year of 1987. The plant will continue its pollution prevention program to develop emission reduction projects resulting in a significant, permanent, and verifiable decrease in the amount of regulated pollutants emitted. Since there is no current or anticipated regulatory requirement to implement any of the types of projects being considered, all emission reductions that occur would represent a significant benefit to the environment that would not be realized as a result of current regulatory programs. The size of the overall plantwide reduction in emissions is dependent on the nature of final projects. Each project will be financially reviewed to ensure that the most effective projects are selected. Cost effectiveness will be dependent, in part, on the amount of regulatory relief provided in the Final Project Agreement.

Merck proposes establishing a plantwide emission cap based on the actual total annual tonnage of regulated pollutants emitted before implementation of the project reductions. Merck would use any VOC, SO2, NOx, and HCl reductions as pound-for-pound exchange to increase VOC emissions elsewhere in the plant as needed, while remaining under the plantwide cap. Merck would agree to pursue meaningful percentage reductions in the cap over time and/or implement other projects beneficial to the environment as a part of the Final Project Agreement.

Merck proposes that changes in emissions beneath the cap be allowed with a simple administrative update and that state preconstruction permitting be waived for new or modified emitting units that are part of the plant's cap. The overall project would provide significant emission reductions from current actual emissions, while providing the plant with simplified air permitting procedures which will enhance the plant's flexibility and provide state and federal regulatory agencies with a far less resource-intensive permitting process to manage and oversee. Key regulatory issues to be worked out in the course of Final Project Agreement development will include a means of dealing with changes in HAP emissions of varying toxicity that occur under the cap, issues related to the possible sale of credits, and monitoring requirements.

The timing of the initial XL pilot projects overlaps with the plant's anticipated schedule for preparation of a Title V permit application. The resource demands for Title V and Project XL preclude doing both at the same time. Indeed, the structure of an XL-based permit would be so dependent on the specific terms negotiated in the Final Project Agreement that it would be illogical to proceed with a separate standard Title V permit. If Merck was selected to proceed toward a Final Project Agreement, it would be necessary to address Title V requirements or alternatives in the XL-based permit. Our participation in Project XL would be contingent upon the permitting authority's ability to legally defer submittal

of the plant's Title V application until the first round of permit renewals in Virginia or some other time period agreeable to Merck, EPA and the Commonwealth of Virginia.

Project Criteria

EPA, in its 5/23/95 solicitation of XL pilot projects, proposed eight selection criteria to evaluate prospective projects. Merck believes that its draft proposal meets all eight selection criteria:

1. **Environmental results.** The Merck proposal offers substantial voluntary emission reductions relative to current actual emissions. Many of the reductions could be in a category (acid gases) that is a priority for reduction by Shenandoah National Park. SO2 and NOx from both local and distant sources contribute to the Park's visibility problems and both SO2 and HCl aggravate acid rain problems that are adversely affecting Park streams.

Reduced emissions often accompany process improvements. The ability to implement improvements faster through streamlined permitting will also benefit the environment.

The considerable cost of projects like the ones proposed would probably preclude Merck from proceeding voluntarily without substantial regulatory relief. None of the reductions being considered would likely occur through current and reasonably anticipated regulations.

2. **Cost savings and paperwork reduction.** Merck anticipates that the proposed simplified permitting procedures will yield cost savings by speeding the introduction of new products and process improvements for existing products. The ability to do these things quickly maximizes the use of existing capital equipment, helping to defray the cost of the emission reduction projects that made the efficiency improvements possible. Additional savings would result by minimizing the anticipated increase in environmental staff paperwork that is expected to occur under future Title V and Title III requirements. Beyond the savings to Merck, there will be comparable savings in resource demands at both state and federal regulatory levels which will be particularly rewarding for projects which result in either trivial or zero actual increases.

3. **Stakeholder support.** In addition to Merck, the main stakeholders in the project will be the local community, Shenandoah National Park, the Virginia Department of Environmental Quality, EPA Region 3, and EPA Headquarters. Merck has already established contacts with local officials and the Park Service to regularly communicate on

topics of mutual interest. This will be a logical forum to meet with local officials and the Park Service, and it is anticipated that they will enthusiastically support projects like those under consideration.

Merck is also meeting with Virginia environmental officials to request their participation. While a successful project will require considerable effort by Virginia at a time when they have reduced staff in the face of a greatly increased (Title V) workload, the type of permit that can be developed could significantly reduce the state's future resource needs for our facility and for other similar complex operations. By submission of this proposal, Merck is seeking the support of EPA Region 3 and Headquarters .

4. **Innovation/multi-media pollution prevention. (TO BE SUBMITTED LATER)**

5. **Transferability. (TO BE SUBMITTED LATER)**

6. **Feasibility.** Merck has the financial and administrative capability to implement the pollution prevention/reduction projects anticipated in the Final Project Agreement. Technical feasibility will be addressed later.

7. **Monitoring, reporting, and evaluation.** The project will challenge all stakeholders to come up with effective and reasonable monitoring schemes to show continuous compliance with a cap. If the effort saved by streamlining permitting procedures is simply transferred to increased monitoring, record keeping, and reporting tasks, any net savings in administrative efforts could be negated. Merck feels that agreement on enforceability issues will be one of the most challenging aspects of the project.

8. **Shifting of risk burden.** The proposed project is consistent with Executive Order 12898 on Environmental Justice. Reductions in emissions at the Stonewall Plant will not result in increased emissions elsewhere.

Merck commends the EPA on this common sense approach to environmental regulation and looks forward to developing this innovative regulatory concept in a spirit of mutual cooperation with all the stakeholders. Project XL can result in substantial environmental improvements that would not otherwise occur. We believe that the flexibility advantages afforded the plant by such a project will enhance its competitive position well into the 21st century, while providing substantial environmental improvement consistent with Merck's commitment to environmental excellence.

Merck & Co., Inc.
P.O. Box 7
Elkton VA 22827
Tel 703 298 1211

August 25, 1995

MERCK
Manufacturing Division

Mr. Jon Kessler
Office of Policy, Planning and Evaluation
United States Environmental Protection Agency
West Tower 1013, Mail Code 2111
401 M Street, SW
Washington, DC 20460

RE: Merck Project XL Application

Dear Mr. Kessler:

To supplement the information included in our August 4, 1995 Project XL application, Merck & Co., Inc. wishes to take this opportunity to clarify and expand on the initial submittal.

Avoiding increased risk

Merck recognizes that any plantwide emission cap negotiated in Project XL would require limits that provide reasonable assurance that increased risk to the environment or individuals does not result from the project. The project, as Merck currently envisions it, will likely involve interpollutant trading. A portion of the emission reductions achieved by the project would be reserved as credits for possible emission increases to accommodate the future growth of the Stonewall Plant. The reductions would be largely composed of SO2, NOx, HCl, and to a lesser extent VOCs while most future increases would likely be composed of VOCs. Since the relative risks of the various criteria pollutants are not well established, Merck recognizes that a trading plan that assures reduced risk will be difficult to define. Trading on a basis other than "pound for pound" would probably make sense for certain pollutants and is expected to be a subject of negotiation if Merck is selected to pursue a final project agreement.

Environmental benefits

The Merck project will provide environmental improvement both in terms of reduced human health risk as well as protection of the adjacent Class 1 area. For example, if a powerhouse emission reduction project is chosen, the environment will benefit by a reduction of hazardous air pollutants (hydrochloric acid and hydrogen fluoride), substantial decreases in SO2, and considerable NOx reductions. Since ground level ozone formation in rural areas is generally

NOx limited, nearby NOx reductions might result in decreased ozone formation in the Class 1 area and elsewhere.

Apart from emission reductions derived from pollution reduction projects, a plantwide emission cap could provide a regulatory mechanism to provide incentives for pollution prevention which will minimize actual emissions for the plant over the long term. We believe this approach is needed in an increasingly competitive worldwide market.

Baseline

The baseline emissions for the project would be recent actual emissions during periods of representative production activities, and would be subject to negotiation. We would not mean to imply that 1987 TRI emissions would comprise a reasonable baseline. We would expect that the baseline would be subject to adjustment in the future to reflect new requirements, including the pharmaceutical MACT.

Accountability

Merck understands the need for accountability in a project of this type, and would commit to establish monitoring and reporting protocols sufficient to provide high assurance that emission reductions are real and permanent and that any established cap is not exceeded.

Stakeholder support

The Merck project has received strong interest from the VADEQ and the National Park Service. Due to the benefits derived from emission reductions associated with the project and the anticipated enhanced economic viability of the Plant due to the increased operational flexibility afforded by a plantwide cap, we expect strong local support. A meeting with our local community advisory panel will be held in the near future to discuss our possible participation in Project XL.

I hope this letter will help to clarify our proposal. If I can provide any further clarification or additional information, please don't hesitate to contact me.

Sincerely,

Tedd H. Jett, P.E.
Stonewall Plant Environmental Manager

cc: Steve Harper (by FAX)

Merck & Co., Inc.
P.O. Box 7
Elkton VA 22827
Tel 703 298 1211

MERCK
Manufacturing Division

July 19, 1995

Mr. Peter W. Schmidt
Director
Department of Environmental Quality
P. O. Box 10009
Richmond, VA 23240-0009

Dear Mr. Schmidt:

In anticipation of our meeting in Richmond on Thursday morning, please find attached a copy of the conceptual outline of our proposal for Project XL. This outline was submitted to EPA, Headquarters today. Ms. Dorothy Bowers. Vice President, Environmental and Safety Policy, Dr. Charles Vencill, Stonewall Plant Manager, and I look forward to reviewing this subject with you and your staff.

Sincerely,

Tedd H. Jett, P.E.
Manager, Environmental Engineering

cc: R. B. Chewning

Attachment