Eli Lilly and Company

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26 June 2024

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

Attention: Compliance and Enforcement Branch, Mr. Janusz Johnson

Certified Mail: 7004 0750 0004 3200 0350

Re: Eli Lilly and Company, Lilly Lebanon Plant
40 CFR 63, Subpart GGG Precompliance Report
Source ID: 011-00084
Agency Interest ID: 133026

Dear Mr. Johnson:

Enclosed please find the Precompliance Report for Eli Lilly and Company's Lebanon Facility.

Eli Lilly and Company's Lebanon Facility is subject to the requirements of 40 CFR Part 63, Subpart GGG, National Emission Standard for Pharmaceuticals Production. Under Subpart GGG, the compliance date for a new source is upon startup. For new construction, the Precompliance report must be submitted at least 90-days before the compliance date, as identified in Table 1 to Subpart GGG.

Under the reporting requirements established in 40 CFR 63.1260(e), each owner or operator of an affected source is required to submit a Precompliance Report. The Precompliance Report must contain the information specified in 40 CFR 63.1260(e)(1) through (7). The Precompliance Report identifies sections of the rule for which Lilly needs IDEM's pre-approval for compliance methodology. This information is included in the enclosed Precompliance Report for the LP1 (Lilly Lebanon API) Plant.

If you have any questions pertaining to the enclosed, please contact Jason Krawczyk at (463) 246-9152 or me at (765) 978-1352.

Sincerely,

Teresa Reksel
HSE Senior Director – Lilly Lebanon API
Eli Lilly and Company

Enclosure

Precompliance Report
for
NESHAP for Pharmaceuticals Production
40 CFR 63, Subpart GGG

Eli Lilly and Company
Lilly Lebanon Facility
LP1 Plant
Lebanon, Indiana

26 June 2024

Background and Purpose

Eli Lilly and Company received a New Source Construction and Part 70 Operating Permit, T011-46484-00084, from the Indiana Department of Environmental Management (IDEM) on 3 May 2024 for its Lilly Lebanon Facility. The Lilly Lebanon Facility consists of two (2) pharmaceutical manufacturing plants, LP1 (Lilly Lebanon API) and LP2 (Lilly Lebanon Advanced Therapies). Since the two (2) plants are located within a contiguous area, belong to the same industrial grouping, and are under common control of the same entity, IDEM, OAQ found that the plants meet all the criteria of the major source definition under 326 IAC 2-7-1(22)(A) and are part of the same Part 70 major source.

Under the National Emission Standard for Pharmaceutical Production (herein identified as Pharma MACT), a new source is a source for which construction commenced after 2 April 1997 and which operates a pharmaceutical manufacturing process unit (PMPU) dedicated to manufacturing a single product that has the potential to emit 10 tons per year of any one hazardous air pollutant (HAP) or 25 tons per year of combined HAP.

Lilly's LP1 Plant will produce intermediate and final bulk pharmaceutical products and will operate a PMPU dedicated to manufacturing a single product that has the potential to emit 10 tons per year of any one HAP or 25 tons per year of combined HAP.

Lilly's LP2 Plant will produce small batch cell and gene therapy pharmaceutical products using aqueous based processes and will not operate a PMPU, as defined at 40 CFR 63.1251. Although part of the same Part 70 major source, the LP2 Plant will not be subject to any requirements under Pharma MACT.

Pharma MACT establishes the maximum achievable control technology (MACT) for HAP emissions from process vents, storage tanks, wastewater management units, and equipment leaks generated during pharmaceutical production operations.

Under the reporting requirements established in Pharma MACT at 40 CFR 63.1260, each owner or operator of an affected source is required to submit a Precompliance Report. The Precompliance Report must contain the information specified in 40 CFR 63.1260(e)(1) through (7), as applicable. The Precompliance Report identifies sections of the rule for which Lilly needs IDEM's pre-approval for compliance methodology. The information included below satisfies the requirements of 40 CFR 63.1260(e)(1) through (7).

(1) Requests for approval to use alternative monitoring parameters or requests to set monitoring parameters according to § 63.1258(b)(4).

Lilly's LP1 Plant will not be requesting approval to use alternative monitoring parameters or to set monitoring parameters according to 40 CFR 63.1258(b)(4).

(2) Descriptions of the daily or per batch demonstrations to verify that control devices subject to §63.1258(b)(1)(i) are operating as designed.

§63.1258(b)(1)(i) requires periodic verification on a daily or per batch basis that control devices, which control vent streams totaling less than 1 ton per year of uncontrolled HAP emissions are operating properly. As part of the current design, Lilly's LP1 Plant will not have individual vent streams totaling less than 1 ton per year being routed to control devices. Therefore, none of the planned control devices will be subject to this provision.

(3) A description of test conditions, and the corresponding monitoring parameter values for parameters that are set according to § 63.1258(b)(3)(ii)(C).

Lilly's LP1 Plant will not be establishing any parametric monitoring maximum or minimum values according to 40 CFR 63.1258(b)(3)(ii)(C). The LP1 Plant will not be utilizing control devices subject to performance tests. In lieu of performing performance tests on the control devices to determine compliance with emission limitations, Lilly's LP1 Plant process vents will instead utilize Continuous Emissions Monitoring Systems (CEMS). The CEMS will monitor the outlet TOC concentration at least once every 15-minutes during the period in which the control device is functioning in achieving the HAP removal required by the MACT.

(4) For owners and operators complying with the requirements of § 63.1252(e), the P2 demonstration summary required in § 63.1257(f).

Lilly's LP1 Plant will not be using the pollution prevention option in 40 CFR 63.1252(e).

(5) Data and rationale used to support an engineering assessment to calculate uncontrolled emissions from process vents as required in § 63.1257(d)(2)(ii).

Lilly's LP1 Plant will not be using an engineering assessment to estimate uncontrolled HAP emissions.

(6) Data and other information supporting the determination of annual average concentrations by process simulation as required in § 63.1257(e)(1)(ii).

Lilly's LP1 Plant will not be using process simulation for determining annual average concentration of wastewater streams. Lilly relies on the "knowledge of the wastewater stream" provisions at §63.1257(e)(1)(ii)(B)(1) and (B)(2) to determine if the thresholds for HAPs are met to determine affected wastewaters.

(7) Bench scale or pilot-scale test data and rationale used to determine annual average concentrations as required in § 63.1257(e)(1)(ii)(C).

Lilly's LP1 Plant will not be using bench scale or pilot scale test data for determining annual average concentration of wastewater streams.

Inspection and Monitoring of Waste Management Units and Treatment Processes

40 CFR 63.1258(g)(2) applies to biological treatment units used to comply with § 63.1256(g) and states that the owner or operator may request approval to monitor other parameters beyond TSS, BOD, and the biomass concentration at a frequency approved by the permitting authority and using methods approved by the authority. The condition requires the request for alternative parameter monitoring to be included in the Precompliance Report.

40 CFR 63.1258(g)(3) applies to nonbiological treatment units and specifies that the owner or operator shall request approval to monitor appropriate parameters that demonstrate proper operation of the selected treatment process and that the request shall be submitted in the Precompliance Report and shall include a description of planned reporting and recordkeeping procedures.

The requirements at 40 CFR 63.1258(g)(2) and (g)(3) are not applicable, as no wastewater systems at the Lilly Lebanon Facility are needed onsite for Pharma MACT wastewater compliance. All wastewater streams above the HAP point of determination (POD) thresholds will be collected in Resource Conservation and Recovery Act (RCRA) systems and will be shipped to a site that meets the MACT treatment requirements. No Pharma MACT subject wastewater will be sent to the Publicly Owned Treatment Works (POTW).

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