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May 21, 2024

Mr. Michael Cox Michigan Department of Environment, Great Lakes, and Energy Air Quality Division Kalamazoo District Office 7953 Adobe Road Kalamazoo, MI 49009-5025

c. Jenine Camilleri, Enforcement Unit Supervisor

Re: Zoetis Violation Notice Response

Dear Mr. Cox:

Zoetis, Inc. (Zoetis), SRN B7149, submits this letter in response to the May 1, 2024 Violation Notice (VN) to document the corrective actions taken to address the exceedances of the 21-ton per 12-month rolling time period material limit for ethyl alcohol usage contained in Permit to Install (PTI) 30-05C, FGB248COMP, Special Condition II.2. The VN requested specific information be submitted with the response, which follows.

Dates the violations occurred

The 12-month rolling material usage limit of 21 tons of ethyl alcohol was exceeded from May 2020 through January 2023. Zoetis complied with the material usage limit from February 2023 through February 2024.

The 12-month rolling material usage limit was again exceeded starting in March 2024. Due to the nature of the 12-month rolling calculation, this exceedance will continue until the modified PTI 30-05D is issued, as described in the corrective actions section below. Refer to Attachment 1 for the PTI 30-05C Compliance Record updated to include the January 2019 through April 2024 timeframe.

Explanation of the causes and duration of the violations

The exceedance of the 12-month rolling ethyl alcohol material usage limit was discovered when Zoetis contracted Barr Engineering Co. (Barr) to complete a PTI 30-05C compliance review during 2023. Barr evaluated site records, re-evaluated and, in most cases, recalculated emission factors for the current product suite, and developed an updated recordkeeping methodology to evaluate compliance with the limits in PTI 30-05C, including the 12-month rolling ethyl alcohol material usage limit.

Historically, monthly recordkeeping of the isopropyl alcohol usage and ethyl alcohol usage were obtained from liquid transfer information within the Systems, Applications and Products in Data Processing (SAP) system at Zoetis' Kalamazoo facility. Prior to 2019, Zoloft was the primary product using ethyl alcohol as a raw material; the ethyl alcohol used for Zoloft production was stored in a dedicated bulk tank. Following

the transition from Zoloft to the current suite of products, the ethyl alcohol bulk tank was switched to isopropyl alcohol service in 2019.

Two of the current products, Antirobe and Triamulox, use raw materials containing ethyl alcohol. Triamulox uses higher amounts of ethyl alcohol per batch; by comparison, Antirobe uses a significantly smaller amount per batch. Both of those raw materials are received and stored in drums. Following the transition away from Zoloft production, no ethyl alcohol usage from drum stock was tracked during the period May 2019 through December 2020; however, Triamulox production was occurring in 2019 and 2020. Zoetis believes that the tracking system was only pulling ethyl alcohol usage associated with transfers from the bulk ethyl alcohol tank used for Zoloft, which was discontinued in May 2019.

## Status of violations

As described above, the 12-month rolling ethyl alcohol material usage limit exceedance will continue until a modified PTI is issued. As described below, Zoetis has submitted an application to modify PTI 30-05C in order to increase the 12-month rolling ethyl alcohol material usage limit to a level consistent with past and future projected Triamulox production levels.

Corrective actions and completion dates

To address the exceedance of the rolling 12-month ethyl alcohol material limit, Zoetis has taken the following actions:

- May 15, 2024
  - Submitted a PTI application to modify PTI 30-05C to:
    - Update and expand emission unit descriptions to align with the liquid compounding equipment covered by the permit and to be consistent with emission unit descriptions in other recently updated facility PTIs;
    - Revise emission control equipment descriptions and operating conditions to reflect current add-on emission controls on-site; and
    - Increase the ethyl alcohol material limit to align with current and projected future production levels.
- May 20, 2024
  - Implement use of the updated PTI 30-05C recordkeeping tool to calculate volatile organic compound (VOC) emissions and material usage based on the number of production batches, rather than reliance on SAP coding.

Steps being taken to prevent a reoccurrence

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The exceedance will be corrected once the PTI modification is complete and PTI 30-05D is issued.

To avoid recurrence of the recordkeeping oversight the monthly recordkeeping tracker is now tied to the number of production batches occurring per month, while also including the material usage levels and emission factors associated with each batch. Furthermore, if raw material SAP coding changes occur, the recordkeeping will not be affected because material usage and the resulting emissions are tied to the number of production batches and the product recipes.

Additional information

The PTI 30-05C compliance review completed by Barr determined that Zoetis' processes have operated in compliance with both the isopropyl alcohol material limit of 3,440 tons per 12-month rolling period and the VOC emissions limit of 17.5 tons per 12-month rolling period throughout the timeline, even with the increased ethyl alcohol usage (Attachment 1). The additional ethyl alcohol usage did not impact compliance with the VOC emissions limit because the current products using ethyl alcohol are lower emitting than the prior products. Emission factors for the current product suite were re-evaluated and recalculated where appropriate.

Barr also evaluated the increased ethyl alcohol usage and maximum projected emission rate from the current products against the Michigan Toxic Air Contaminants (TAC) screening levels under Michigan Administrative Rule 227, which is the referenced regulatory basis for the ethyl alcohol material limit in condition II.2 of PTI 30-05C,

Rule 227 establishes the method for determining the maximum allowable emission rate of a TAC based on its health-based screening level. For ethyl alcohol (ethanol), the applicable initial threshold screening level (ITSL) is 19,000 µg/m³ with a 1-hour averaging time. Per Rule 227, the allowable emission rate calculated from that ITSL is 19 pounds per hour (lb/hr). The maximum emission rate calculated by Emission Master during the Triamulox process is 4.19 lb/hr, although the process does not emit at that rate for a full hour. The average hourly emission rate for Triamulox and Antirobe combined is 2.11 lb/hr (i.e., if both processes are occurring simultaneously). Therefore, the maximum ethyl alcohol emission rate during Triamulox production is only 22.5% of the allowable emission rate of ethyl alcohol. Based on the Rule 227 analysis, the past and current production levels would not result in ambient impacts that exceed the ethyl alcohol screening level.

Please contact Joshua Coy of Zoetis at <u>joshua.coy1@zoetis.com</u> or (269) 220.8383, or Brian Greenwald of Barr at <u>bgreenwald@barr.com</u> or (616) 512.7012, to discuss this response or to schedule a meeting to discuss this matter in more detail.

Sincerely

Ayron Stagray

Enclosed:

Site Lead

Attachment 1: PTI 30-05C Compliance Record - January 2019 through April 2024

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