

REPORT OF RCRA COMPLIANCE EVALUATION INSPECTION

At

ELANCO FORT DODGE

800 5th Street NW

Fort Dodge, Iowa 50501

515-302-2049

EPA ID Number: IAD005290259

On

June 5, 2024

By

TOEROEK ASSOCIATES, INC.

For

U. S. ENVIRONMENTAL PROTECTION AGENCY

Region 7

Enforcement and Compliance Assurance Division

INTRODUCTION

At the request of the Enforcement and Compliance Assurance Division/Chemical Branch/RCRA Section (ECAD/CB/RCRA) of the U. S. Environmental Protection Agency (EPA) Region 7, Toeroek Associates, Inc., and its subcontractor CLAENE Group (Toeroek team) conducted a hazardous waste compliance evaluation inspection (CEI) at Elanco Fort Dodge (Elanco) at 800 5th Street NW, Fort Dodge, Iowa. The CEI was conducted under the authority of Section 3007 of the Resource Conservation and Recovery Act (RCRA), as amended. The CEI covered hazardous waste generator requirements, used oil management, and universal waste requirements, as applicable. This report and its attachments present the results of the CEI.

PARTICIPANTS

Elanco:

Gretchen Knott, Director, Health, Safety, and Environmental (HSE)

Jessica Moffitt, Senior Associate, HSE

Joshua Claussen, Consultant, Health and Safety

Toeroek Team:

Clifford Nelles, Inspector, 816-213-5192

INSPECTION PROCEDURES

Prior to the CEI at Elanco on June 5, 2024, I conducted a drive-by visual inspection. I did not observe any areas of concern during the drive-by. Upon my arrival, I entered the visitor's entrance and explained the purpose of the CEI to the reception attendant. I asked to speak with Ms. Knott, who was listed as the site contact on the Notification Acknowledgement/Verification Report (Verification Report) provided by EPA (Attachment 1). The reception attendant contacted Ms. Knott who, along with Ms. Moffitt and Mr. Claussen, met me in the lobby area approximately five minutes later. I introduced myself to Ms. Knott, Ms. Moffitt, and Mr. Claussen (the Elanco team) and explained the purpose of the CEI to them. We then went to a conference room where I conducted an entry briefing with the Elanco team.

During the entry briefing, I presented my business card and EPA credentials to the Elanco team. I explained the scope and procedures for the CEI. I explained the facility's right to make confidentiality claims for any or all the information obtained and provided a Notice Regarding Proprietary/Confidential Business Information. I stated that at the conclusion of the CEI, Ms. Knott would be presented with a Confidentiality Notice (Notice) with which she could make or not make a claim of confidentiality for the facility. I also provided the Elanco team a copy of U.S. Federal Codes 1001 and 1002, concerning communication of false statements and documents to federal inspectors, and RCRA Section 3007, explaining EPA's inspection authority, both of which they read.

A copy of each of the following documents was left with Ms. Knott during the inspection:

- RCRA Facility Access Information Sheet
- RCRA Section 3007
- U.S. Federal Codes 1001 and 1002
- Notice Regarding Proprietary/Confidential Business Information
- Notice of Responding to a Notice of Preliminary Findings

The following handouts were emailed to Ms. Knott after the CEI.

- E-Manifest Fact Sheet: Generators
- Managing your Hazardous Waste: A Guide for Small Businesses
- U.S. EPA Small Business Resources Information Sheet
- Solvent-Contaminated Wipes Final Rule Summary Chart
- IDNR Excluded Solvent-Contaminated Wipes Rule: Management Practices for Wipes, Rags, and Shop Towels
- Recycling Electronics: A Guide for Businesses
- Lead-Based Paint Activities: Handling and Disposal
- Battery Recycling/Disposal
- Management of Fluorescent Lamps for Businesses
- Incompatible Chemicals
- Universal Wastes – Including Aerosol Cans
- TCLP – Toxicity Characteristic Leaching Procedure
- Part 279 Requirements: Used Oil Management Standards
- EPA Region 7 Emergency Response Program

- Chemical Facility Anti-Terrorism Standards
- Iowa Environmental Guide for Businesses

I reviewed the Verification Report with Ms. Knott during the entry briefing (Attachment 1). Based on this review, I made no changes to the Verification Report.

I conducted a visual inspection of the facility, accompanied by the Elanco team. Following the visual inspection, I reviewed facility records including hazardous waste manifests with land disposal restriction (LDR) notifications, safety data sheets (SDS), contingency plan, inspection records, and training documentation. I prepared and completed a site-specific inspection checklist to document my observations.

At the conclusion of the CEI, I conducted an exit briefing with the Elanco team. During the exit briefing, I provided a Receipt for Documents and Samples, which Ms. Knott signed, acknowledging receipt (Attachment 2). I provided Ms. Knott the Notice, which she signed indicating no confidential business information had been provided (Attachment 3). I also provided Ms. Knott a Notice of Preliminary Findings (NOPF) (Attachment 4), which she signed to acknowledge receipt. Maps of the facility obtained during the CEI are included in Attachment 5, and a Google Earth aerial photograph of the facility is included as Attachment 6. The 42 photographs taken during the CEI are included in Attachment 7, of which 38 are described in this report.

FINDINGS AND OBSERVATIONS

1. Facility Description and General Information

Elanco has been operating at its current location since approximately 1917. Elanco currently employs approximately 400 personnel who work one of three 8-hour shifts (6:00 a.m. to 2:00 p.m., 2:00 p.m. to 10:00 p.m., or 10:00 p.m. to 6:00 a.m.) Monday through Friday or 12-hour shifts (6:00 a.m. to 6:00 p.m. or 6:00 p.m. to 6:00 a.m.) Friday through Sunday. The facility consists of 55 buildings with approximately 700,000 square feet under roof. Building 115 contains most of the production area of the facility.

Elanco is an animal health pharmaceutical company that produces vaccines and medication for livestock and domesticated pets. The major raw materials used are biological media, acids, bases, viral and bacterial stock. Thimerosal (an organomercury compound) is used as a vaccine preservative. The major manufacturing or processing operations that generate waste streams include cleaning bioreactors, fermenter vessels, and various other production equipment, producing vaccines, lab waste, and quality control sampling waste.

Wastes generated during manufacturing or processing operations include rinse water containing thimerosal waste, thimerosal debris, flammable waste, lab pack waste, waste vaccine, and waste caustic. The facility considers each of these waste streams to be hazardous based on product and process knowledge. Cleaning of bioreactors and fermenter vessels also generates derouging solution, which is considered nonhazardous based on analytical testing.

Facility and equipment maintenance activities generate used aerosol cans, used oil, waste batteries, waste lamps, and general trash. Aerosol cans are considered to be hazardous based on product and process knowledge. The facility manages used oil according to provisions of Title 40 *Code of Federal Regulations* (40 CFR) Part 279. Waste batteries and lamps are managed as universal waste according to provisions of 40 CFR Part 273. The facility considers general trash to be nonhazardous based on product and process knowledge.

Elanco was last inspected by an EPA contractor on November 17, 2020, with the following preliminary findings.

- Failure to include where hazardous waste is generated or managed and access to these locations in the Quick Reference Guide, as required by 40 CFR 262.262(b)(4)
- Failure to include primary route and alternate route in the evacuation plan submitted as part of the contingency plan, as required by 40 CFR 262.261(f)

None of the findings were repeated in this inspection. Other than items specifically noted in the narrative, I observed no additional issues. However, further review by EPA may change or add to my findings.

2. RCRA Status

Elanco is identified as a large quantity generator (LQG) on the Verification Report provided by EPA (Attachment 1), generating more than 1,000 kilograms (kg) or 2,200 pounds of hazardous waste per month. Based on the 2023 Hazardous Waste Biennial Report (Attachment 8, page 3, Generation and Management [GM] waste 3), the facility generates approximately 82,386 pounds (37,370 kg) per month of rinse water containing thimerosal alone. Uniform hazardous waste manifest records over the previous 3 years support the generation rate in the Biennial Report. Therefore, I determined the facility is operating as a LQG of hazardous waste and inspected the facility as such. I also inspected Elanco as a used oil generator and a SQH of universal waste (accumulating less than 5,000 kg of universal waste at any time).

The facility operates three less-than-90-day hazardous waste central accumulation areas (HWCAAs). The three HWCAAs are in Building 125, Room 91; Building 130, Room 222; and Building 115, Room 854. Building 115 also houses the facility's aboveground storage tank (AST) for hazardous waste. I inspected each of these HWCAAs and the hazardous waste AST during the CEI. I also inspected 11 of the 23 satellite accumulation areas (SAAs) in the production and laboratory areas.

3. Waste Streams

This section of the CEI report describes the waste streams generated by the facility, including the facility's waste determination and waste codes, generation process and rate, management at the facility, and ultimate disposition. The following discussion of waste streams is based on conversations with facility representatives, the visual inspection, and my review of waste shipping documents. The Elanco team accompanied me throughout the CEI. All participants were provided a copy of U.S. Federal Codes 1001 and 1002.

Rinse water containing thimerosal is generated during cleaning of bioreactor fermenter vessels and quality control. The 2023 Biennial Report includes any liquid thimerosal waste generated at the facility with this waste stream. Based on the 2023 Biennial Report (Attachment 8, page 3, GM 3), the facility generates approximately 82,386 pounds (37,370 kg) of rinse water containing thimerosal per month. The facility considers the waste to be characteristic (D009) hazardous waste based on process and product knowledge. A copy of the SDS for thimerosal (which was provided after the CEI) is included as Attachment 9. Based on the SDS, it appears the waste determination is adequate. The waste is accumulated in 55-gallon hazardous waste accumulation containers (HWACs) or a 10,000-gallon hazardous waste AST in Building 115. Rinse water containing thimerosal waste is transported to Clean Harbors in Kimball, Nebraska, or Reedsville, North Carolina, for incineration.

A list of SAAs at the facility is included as Attachment 10. I used this list to select a representative number of SAAs for inspection. During the CEI, I observed a 55-gallon satellite accumulation container (SAC) of liquid thimerosal waste in Building 115, Room 662 (Attachment 7, Photograph 3) and a 5-gallon SAC of liquid thimerosal waste in Building 130, Room 357 (Attachment 7, Photograph 7). Both SACs were near the point of generation, under control of the operator, structurally sound, labeled with the words “hazardous waste” and an indication of the nature of the hazard, and closed. The Building 115, Room 662 SAC held approximately 12 gallons of waste and the Building 130, Room 357 SAC held approximately 3 gallons of waste.

In the Building 125, Room 91 HWCAA, I observed a 120-gallon poly HWAC of liquid thimerosal waste (Attachment 7, Photographs 8 through 10). The HWAC was structurally sound, closed, labeled with the words “hazardous waste” and an indication of the nature of the hazard, dated May 30, 2024, and held approximately 50 gallons of waste.

In the Building 130, Room 222 HWCAA, I observed one 55-gallon and two 5-gallon HWACs of liquid thimerosal waste (Attachment 7, Photographs 19 through 21). The HWACs were structurally sound, closed, labeled with the words “hazardous waste” and an indication of the nature of the hazard, and dated. The accumulation start dates ranged from May 21 to May 28, 2024.

In the Building 115, Room 854 HWCAA, I observed one 300-gallon and four 55-gallon HWACs of liquid thimerosal waste (Attachment 7, Photographs 22, 23, and 30 through 33). The HWACs were structurally sound, closed, labeled with the words “hazardous waste” and an indication of the nature of the hazard, and dated. The accumulation start dates ranged from May 5 to June 5, 2024.

During the CEI, I observed the 10,000-gallon hazardous waste AST in Building 115 for rinse water containing thimerosal (Attachment 7, Photograph 29). The AST is filled by rinsing and draining containers of thimerosal contaminated waste in Building 115 (Attachment 7, Photograph 5). The AST was structurally sound, labeled with the words “hazardous waste” and an indication of the nature of the hazard, closed, and held approximately 3,199 gallons of waste. The AST was last RCRA empty on May 29, 2024. I did not observe any deficiencies related to

management of rinse water containing thimerosal waste or liquid thimerosal waste during the CEI.

Thimerosal debris is generated by the cleaning of equipment and disposal of personal protective equipment (PPE). The facility considers thimerosal debris to be characteristic (D009) hazardous waste based on product and process knowledge. Based on the 2023 Biennial Report (Attachment 8, page 4, GM 4), the facility generates approximately 4,037 pounds (1,831 kg) of thimerosal debris per month. The waste is accumulated in 55-gallon SACs upon generation. Thimerosal debris is transported to Clean Harbors in Kimball, Nebraska, or Reedsville, North Carolina, for incineration.

During the CEI, I observed a SAC of thimerosal debris in Building 115, Room 663 (Attachment 7, Photographs 1 and 2). The SAC was structurally sound, near the point of generation, under control of the operator, labeled with the words “hazardous waste” and an indication of the nature of the hazard, closed, and held approximately 15 gallons of waste. I also observed SACs of thimerosal debris in Building 115, Room 2521; Building 115, Room 607; and Building 115, Room 713. All of these SACs were structurally sound, near the point of generation, under control of the operator, labeled with the words “hazardous waste” and an indication of the nature of the hazard, closed, and held approximately 15 to 30 gallons of waste each.

During the CEI, I observed three 55-gallon HWACs of thimerosal debris in the Building 125, Room 91 HWCAA (Attachment 7, Photographs 11, 13 and 16). The HWACs were structurally sound, closed, labeled with the words “hazardous waste” and an indication of the nature of the hazard, and dated. The accumulation start dates ranged from May 21 to June 3, 2024. I noted no deficiencies related to management of thimerosal debris during the CEI.

Aerosol cans are generated during maintenance of facility equipment and buildings. The facility considers aerosol cans to be characteristic (D001) hazardous waste based on product and process knowledge. Based on interviews with facility representatives, the facility generates approximately 5 pounds of aerosol cans per month. The facility accumulates aerosol cans in 55-gallon SACs. The waste is transported to Clean Harbors (various locations) for bulking and offsite transport.

During the CEI, I observed a 55-gallon SAC of aerosol cans in the Building 115, Room 854 HWCAA (Attachment 7, Photographs 27 and 28). The SAC was structurally sound, near the point of generation, under control of the operator, labeled with the words “hazardous waste” and an indication of the nature of the hazard, closed, and held approximately 15 gallons of aerosol cans. I noted no deficiencies with management of aerosol cans during the CEI.

Flammable waste is generated during the process of laboratory analysis and cleaning of equipment. Flammable waste is considered characteristic and listed (D001 and F003) hazardous waste based on process and product knowledge. Based on the 2023 Biennial Report (Attachment 8, page 4, GM 5 and GM 7), the facility generates approximately 448 pounds (203 kg) of flammable waste per month. The waste is accumulated in 5-gallon SACs, and full

SACs are transferred to a HWCAA. The waste is collected by Safety-Kleen and transported to Safety-Kleen in Smithfield, Kentucky, for fuel blending.

During the CEI, I observed 5-gallon SACs of flammable waste at Building 115, Room 2526 (Attachment 7, Photograph 4) and Building 125, Rooms 37, 38, and 75. The SACs were structurally sound, near the point of generation, under control of the operator, labeled with the words “hazardous waste” and an indication of the nature of the hazard, closed, and held approximately 3 to 4 gallons of flammable waste each.

I also observed a HWAC of isopropyl alcohol (IPA) in the Building 115, Room 854 HWCAA (Attachment 7, Photographs 38 and 39). The HWAC was structurally sound, closed, labeled with the words “hazardous waste,” dated May 11, 2024, and held approximately 2 gallons of waste IPA. However, the HWAC was not labeled with an indication of the nature of the hazard, as required by 40 CFR 262.17(a)(5)(i)(B) (**NOFF No. 1**). I provided compliance assistance regarding labeling requirements for HWACs during the CEI.

Lab packs are generated during production, research and development, and quality control analysis of materials. The facility considers lab pack waste to be characteristic and listed (D001, D002, D004, D009, D022, F003, U002, U003, U044, U122, U154, and U188) based on product and process knowledge. Based on the 2023 Biennial Report (Attachment 8, page 3, GM 1 and GM 2), the facility generates approximately 295 pounds (134 kg) of lab pack waste per month. The lab packs are transported to Clean Harbors in Kimball, Nebraska, for incineration. I did not observe any lab packs in accumulation during the CEI.

Waste vaccine is generated when vaccines have exceeded their expiration date, been stored improperly, or are returned by customers. Based on the 2023 Biennial Report (Attachment 8, page 4, GM 6), the facility generates approximately 4,005 pounds (1,817 kg) of waste vaccine per month. Waste vaccine is transported to Clean Harbors in Kimball, Nebraska, for incineration or bulking and offsite transport.

During the CEI, I observed approximately 624 containers of waste vaccine on 26 pallets in the Building 115, Room 854 HWCAA (Attachment 7, Photographs 34 through 37). All of the HWACs were structurally sound, closed, labeled with the words “hazardous waste” and an indication of the nature of the hazard, and dated April 26, 2024. I noted no deficiencies related to management of waste vaccine during the CEI.

Waste batteries are generated by maintenance personnel replacing spent batteries. Elanco manages waste batteries as universal waste according to provisions of 40 CFR Part 273. Waste batteries are accumulated in universal waste accumulation containers in Building 115, Room 854; Building 185, Room 191N; Building 125, Room 92; Building 130, Room 222; and Building 150, Room 103. According to Ms. Knott, the facility generates approximately 42 pounds of waste batteries per month. The waste is transported to Veolia Environmental Services in Port Washington, Wisconsin, for recycling.

During the CEI, I observed universal waste batteries containers in Building 150, Room 103 (one container) and Building 115, Room 854 (three containers) (Attachment 7, Photographs 6, 17, 18,

and 26). Each container held approximately two gallons of waste batteries, and was structurally sound, labeled with the words “used batteries” and/or “universal waste batteries,” and dated. Accumulation start dates ranged from August 25, 2023 to May 20, 2024. I noted no deficiencies related to management of waste batteries during the CEI.

Used oil is generated during maintenance of equipment. The facility manages used oil according to provisions of 40 CFR Part 279. The facility generates approximately 50 gallons of used oil per month. Used oil is accumulated in 55-gallon containers and transported to Spring Grove Resource Recovery in Cincinnati, Ohio, for recycling. I did not observe any used oil in accumulation during the CEI.

Waste caustics consist of acids and bases that have become contaminated and can no longer be used. A copy of the SDS for One Reagent Stock Solution is included as Attachment 11. The facility considers waste caustics to be characteristic (D002) hazardous waste based on product and process knowledge. Based on the 2023 Biennial Report (Attachment 8, page 5, GM 8 and GM 9), the facility generates approximately 230 pounds (104 kg) of waste caustics per month. Waste caustics are transported to Clean Harbors in Kimball, Nebraska, or Reedsville, North Carolina, for fuel blending or bulking and offsite transport.

During the CEI, I observed a 5-gallon HWAC of phosphoric acid, 1-quart HWAC of hydrochloric acid, and seven 1-pint HWACs of hydrochloric acid in the Building 115, Room 854 HWCAA (Attachment 7, Photograph 40). All of the HWACs were structurally sound, closed, labeled with the words “hazardous waste” and an indication of the nature of the hazard, and dated. The phosphoric acid and the 1-quart of hydrochloric acid were dated June 04, 2024, and the seven 1-pint HWACs were dated May 28, 2024. I did not observe any deficiencies related to management of waste caustics during the CEI.

Waste lamps are generated when maintenance changes out spent lamps. The facility manages waste lamps as universal waste according to provisions of 40 CFR Part 273. The facility generates approximately eight waste lamps per month. Waste lamps are transported to Clean Harbors in El Dorado, Arkansas, for recycling.

During the CEI, I observed a universal waste lamps accumulation container in the Building 115, Room 854 HWCAA (Attachment 7, Photograph 24). The container was structurally sound, closed, labeled with the words “universal waste lamps,” dated December 22, 2023, and held approximately 50 four-foot waste lamps. I did not observe any deficiencies related to management waste lamps during the CEI.

Derouging solution is generated during the cleaning of stainless steel bioreactors and fermenter vessels. Ms. Knorr stated that the facility had recently done this for the first time, creating a waste derouging solution. I did not determine what chemicals were used during the cleaning process. During the CEI, I observed two 300-gallon containers of derouging solution in the Building 115, Room 854 HWCAA (Attachment 7, Photographs 41-42). The containers were structurally sound, closed, labeled with the words “hazardous waste pending analysis,” and dated May 15, 2024. The derouging solution was generated on May 15, 2024, and samples were collected for analysis on May 28, 2024. The analytical report, received on June 10, 2024,

indicated that the derouging solution was nonhazardous. A copy of the analytical report is included as Attachment 12.

General trash consists of nonhazardous production wastes, packaging wastes, and general office-type refuse. General trash is considered nonhazardous and is accumulated in roll-off containers outside the facility. General trash is collected for disposal by Pederson Sanitation and Recycling in Fort Dodge, Iowa for landfilling at the Webster County landfill. I observed accumulation of general trash during the CEI and noted no deficiencies.

4. Required Response Equipment and Hazard Management

Per 40 CFR 262.15(a)(8) and 262.17(a)(6), a LQG must operate to minimize the possibility of a fire, explosion, or spill, and must maintain emergency response equipment. During the visual inspection, I observed spill response equipment comprised of mats, absorbent materials, shovels, and brooms, as well as the presence and availability of fire extinguishers. I determined that the spill and fire response equipment was adequate for the hazardous wastes generated and accumulated at the facility.

5. Container Accumulation Areas

Elanco maintains three HWCAAs and an AST of hazardous waste. The three HWCAAs are in Building 125, Room 91; Building 130, Room 222; and Building 115, Room 854.

According to Ms. Knott, all three of the HWCAAs are inspected weekly, and a log is updated for each inspection. I reviewed three years of inspection logs and verified that the inspections were conducted on a weekly basis. I did not observe any gaps of longer than one week in the inspection logs. A copy of the inspection log for May 15 through May 29, 2024 for all three HWCAAs is included as Attachment 13. I asked Ms. Knott how someone would summon emergency assistance in the HWCAAs. She stated that all of the workers that handle hazardous waste carry two-way radios.

6. Manifests and Biennial Report

Elanco generated manifests for 165 hazardous waste shipments from time period of June 3, 2021, to June 3, 2024. During the CEI, I reviewed manifests and LDR notifications for five shipments in 2021, five in 2022, five in 2023, and seven in 2024. A copy of the manifest log from June 3, 2021 through June 3, 2024 is included as Attachment 14. Copies of the manifests and LDR notifications for shipments dated March 7 and May 16, 2024, are included as Attachment 15 as examples. A copy of the 2023 Biennial Report is in Attachment 8. I noted no deficiencies during my review of manifests, LDR notifications, and the 2023 Biennial Report.

7. Hazardous Waste Tank

Elanco has one 10,000-gallon AST on site used for accumulation of rinse water containing thimerosal waste. Tank (TK10400001) is located in Building 115, Room 854 (Attachment 7, Photograph 29). Waste is added to the tank via a drain and rinse station directly above and connected to the AST (Attachment 7, Photograph 5). The tank, secondary containment, building,

and surrounding areas appeared to be in good condition with no evidence of leaks or spills. The tank began accumulating hazardous waste in 2013, and was assessed by a third-party professional engineer on May 3, 2013. The 10,000 gallon tank was last RCRA empty on May 29, 2024. I asked Ms. Moffitt if the tank was inspected. She stated that the tank is inspected every day. I observed the daily inspection log from June 3, 2021 through June 3, 2024 and noted no deficiencies.

8. Preparedness and Prevention Plan

LQG facilities are required by 40 CFR 262.17(a) to meet the emergency preparedness, prevention, and procedures requirements including documented arrangements with response agencies. According to Ms. Knott, Elanco is the subject of a regular inspection by the Fort Dodge Fire Department hazardous materials team. She explained the fire department is shown the layout of the facility, the location of the hazardous waste HWCAA, and other facility features during inspections.

The facility's contingency plan was last updated May 11, 2024. I reviewed the contingency plan against the content requirements of 40 CFR 262.261. I noted the contingency plan included a description of actions needed to respond to fires, explosions, and spills, a description of arrangements with the local emergency agencies, a list of emergency response equipment (including capabilities and location), and a complete evacuation plan with a description of the signals used, as required by 40 CFR 262.17(a)(6) referencing 262.261(a, c, e, and f). The contingency plan included telephone numbers of the primary emergency coordinator, Ms. Knott, as required by 40 CFR 262.17(a)(6) referencing 262.261(d). A copy of the contingency plan contact information is included as Attachment 16.

The contingency plan also included a quick reference guide, as required by 40 CFR 262.17(a)(6) referencing 262.262(b). I noted no deficiencies with the facility's emergency preparedness, prevention, and procedures during the CEI, including content of the contingency plan and quick reference guide.

9. Personnel Training Requirements

Personnel training is required by LQG regulations specified in 40 CFR 262.17(a)(7) to ensure that employees are thoroughly familiar with proper waste handling procedures relevant to their responsibilities. During the CEI, I asked Ms. Knott if hazardous waste training is provided to employees. She stated that hazardous waste training is provided to all employees who handle hazardous waste within six months of hiring or being assigned to a job that handles hazardous waste. He also stated that annual refresher training is conducted. I asked Ms. Knott who conducts the training. She stated that the training is conducted online through Lion Technology. I reviewed the training records for the last three years for Ms. Knott and Ms. Moffitt. Copies of the certificates and training records for Ms. Knott and Ms. Moffitt for the last three years are included in Attachment 17 as examples.

I reviewed the written job descriptions for Ms. Knott and Ms. Moffitt and noted that they appeared to meet requirements of 40 CFR 262.17(a)(7)(iv). Copies of the job descriptions for Senior Associate, HSE, and Director, HSE are included as Attachment 18.

10. Air Emissions: 40 CFR Part 265 Subparts AA, BB, CC

EPA regulations in 40 CFR Part 265, Subparts AA, BB, and CC apply to LQGs. If a LQG manages hazardous waste with an organic concentration greater than 10 parts per million by weight (ppmw), the standards specified in Subpart AA apply to hazardous waste air emissions from certain process vents. A process vent used in distillation, fractionation, solvent extraction, thin-film evaporation, air stripping, or steam stripping is regulated by Subpart AA. Elanco is not subject to the Subpart AA regulations because the facility does not have any of the process vents listed above.

If a LQG has equipment that contains or contacts hazardous waste composed of 10 percent or greater organics by weight, the facility is subject to Subpart BB standards for inspection and monitoring of the equipment. Elanco is not subject to the Subpart BB regulations because it does not have equipment that contains or comes in contact with volatile hazardous waste.

The standards found in Subpart CC apply to LQGs that manage hazardous waste in containers with organic compounds (VOC) concentration that exceeds 500 ppmw. The Subpart CC standards are applicable because the facility accumulates hazardous waste that contains VOCs in 55-gallon HWACs. During the CEI, I determined that Elanco meets the Subpart CC requirements for containers by using Container Level 1 controls (HWACs smaller than 122 gallons that are Department of Transportation [DOT]-approved). I noted no concerns with management of hazardous waste per the Subpart CC air emissions requirements.

11. Summary of Preliminary Findings

In summary, as part of the CEI, I made the following preliminary findings.

- Failure to label a HWAC with an indication of the nature of the hazard as required by 40 CFR 262.17(a)(5)(i)(B) (**NOPF No.1**).

Other than items specifically noted in the narrative, I observed no additional issues. However, further review by EPA may change or add to my findings.

Clifford A.
Nelles

Digitally signed by Clifford
A. Nelles
Date: 2024.07.26
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Date: _____

Clifford A. Nelles, Inspector
CLAENE Group

AMBER WHISNANT

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AMBER WHISNANT
Date: 2024.08.26
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Date: _____

Amber Whisnant, Section Chief
ECAD/CB/RCRA, EPA Region 7

Attachments:

1. Notification/Acknowledgement Verification Report (1 page)
2. Receipt for Documents and Samples (1 page)
3. Confidentiality Notice (1 page)
4. Notice of Preliminary Findings (1 page)
5. Site Maps (2 pages)
6. Google Earth Aerial Photograph (1 page)
7. Photographic Documentation (Photolog and 42 Photographs) (26 pages)
8. Copy of 2023 Biennial Report (6 pages)
9. Copy of SDS for Thimerosal (11 pages)
10. Copy of List of Satellite Accumulation Containers (4 pages)
11. Copy of SDS for One Reagent Stock Solution (15 pages)
12. Copy of Analytical Report for Derouging Solution (13 pages)
13. Copy of Inspection Log for May 15 to May 29, 2024 (3 pages)
14. Copy of Manifest Log from June 3, 2021 to June 3, 2024 (11 pages)
15. Copies of Manifests and LDR for Shipments Dated March 7 and May 16, 2024 (11 pages)
16. Copy of Contingency Plan Emergency Coordinator Contact Information (1 page)
17. Copies of Training Records for Gretchen Knott and Jessica Moffitt for 2022 to 2024 (4 pages)
18. Copies of Job Descriptions for Senior Associate, HSE and Director HSE (4 pages)