

**STATEMENT OF BASIS/ PROPOSED REMEDY AND
REQUEST FOR PUBLIC COMMENTS**

REGION II ID
PRD090346909

Remedy Decision for:
Pfizer Pharmaceuticals, LLC
Barceloneta Facility
Route PR-2, Kilometer (Km) 58.2
Barceloneta, Puerto Rico
(May 24, 2021)

Facility/Unit type: **Pharmaceutical manufacturing processes (site-wide) including treatment, storage and, disposal of liquid hazardous wastes/Solid Waste Management Unit (SWMU) #11 – Former Underground Storage Tank (UST) Farm Area**

Contaminants: **Soil: benzene**
Soil gas: benzene
Groundwater: benzene, chlorobenzene

Media: **Soil, Soil gas, Groundwater**

Remedy: **No Further Action (NFA) with Institutional/Administrative Controls**

FACILITY DESCRIPTION

Pfizer Pharmaceuticals, LLC (Pfizer) Barceloneta facility is located at Route PR-2, Km 58.2 in Barceloneta, Puerto Rico (the Facility), approximately 3.75 miles south of the Atlantic Ocean coast. The land use on adjacent properties is primarily commercial and/or industrial with vacant, forested land to the north and west of the Facility. Commercial and industrial properties border the Facility directly to the east, and Route PR-2 borders the Facility directly to the south. The nearest residential area is located west of the investigated area.

The Facility encompasses approximately 90 acres, which is owned and operated by Pfizer as a pharmaceutical manufacturing facility, including operational buildings, administrative offices, parking lots, and former hazardous waste storage, treatment and disposal areas. Currently, the former Tank Farm – Underground Storage Tank Area (Solid Waste Management Unit [SWMU] #11) is a concrete, covered and lined area with no occupied buildings or current exposure pathways.

HISTORICAL SITE OPERATIONS

Prior to 1972, the Facility property was owned by the Puerto Rico Land Authority and used for growing pineapples. In 1972, Pfizer began construction of the current pharmaceutical manufacturing facility. Pharmaceutical manufacturing operations began in 1973 and the tank farm (i.e., Old Tank Farm) was constructed. The Old Tank Farm originally consisted of 12 underground storage tanks (USTs) situated in concrete foundations backfilled with soil. The tanks were used to store chemicals used in manufacturing processes, including benzene and chlorobenzene.

In 1982, Pfizer expanded the Old Tank Farm to the north (i.e., Expanded Tank Farm), adding six USTs. The tanks in the Expanded Tank Farm were installed within a

concrete containment vault, which was constructed of 6 to 8 inch thick walls and a 9 to 16 inch thick base. The containment vault was backfilled with crushed stone. Sumps were also installed in the containment basin to collect precipitation and any spillage for proper removal and disposal through Pfizer's on-site treatment plant.

In 1984, Pfizer updated the Old Tank Farm in an effort to prevent releases of hazardous substances to the environment. All tanks were removed, inspected and tested, and subsequently reinstalled in a concrete containment basin with a sump to collect and remove rainwater and any spillage or leakage from the tanks. The containment basin was also backfilled with crushed stone.

In 1986, Pfizer applied for a Resource Conservation and Recovery Act (RCRA) Part B permit to store and handle hazardous waste. Pfizer identified 11 SWMUs in the RCRA Part B Permit application.

In August 1988, a RCRA Facility Assessment (RFA) of the Facility was completed and subsequently, surface soil samples were collected from two SWMUs; SWMU #3 and SWMU #11. EPA determined a RCRA Facility Investigation (RFI) was warranted for both SWMU #3 and SWMU #11. No other areas of potential contaminant releases were identified.

Pfizer submitted a revised RCRA permit application on September 15, 1989. In May 1990, EPA issued a RCRA permit, which included a requirement to conduct a RFI at SWMU #11. Based on the results of the RFA, EPA determined that a release of hazardous waste and/or hazardous constituents occurred at SWMU #11. EPA also required a RFI for SWMU #3 if phthalate concentrations were above recommended action levels; however, phthalate levels did not exceed RCRA action levels, so no investigations were performed for SWMU #3.

In April 1993, Pfizer conducted an integrity assessment of the process-water drain pipe near manhole MH-3. A pressure test and camera survey identified a break in the pipe, which was ultimately repaired in May 1993. A follow

up integrity test was conducted in August 1993, which verified pipe integrity after the repair work. Confirmation samples collected during the RFI indicated no volatile organic compounds (VOCs) were present at concentrations above detection limits in the area of the pipeline break.

In 1998, Pfizer decommissioned the Old Tank Farm and constructed an aboveground storage tank (AST) tank farm north of SWMU #11. The new AST tank farm was constructed with a raised bottom and a newly installed containment structure. The decommissioning of the Old Tank Farm included removal, inspection and testing of the USTs and inspection of the concrete containment vault. There were no cracks observed in the concrete floor or walls of the containment vault. Pfizer records indicate standing water was regularly removed from the containment structure. Records also indicate several minor spills of unknown quantities occurred at the Old Tank Farm due to issues with pump seals and pump priming.

Between 1991 and 2006, multiple RFI phases were conducted within SWMU #11 which included: 33 soil test borings (over 100 samples); 26 soil vapor well installations with subsequent rounds of vapor sampling (over 1,000 samples); six groundwater monitoring wells installed with subsequent rounds of groundwater sampling; and, a risk assessment. EPA subsequently requested additional vapor monitoring for benzene and additional groundwater sampling for chlorobenzene. A long-term soil vapor extraction (SVE) system was proposed to remove or diminish the source of benzene and chlorobenzene.

Interim Corrective Measures

Pfizer installed the SVE system and conducted a SVE pilot study from 2015 to 2018 due to the potential risk of benzene in soil vapor. The SVE pilot study determined benzene concentrations met proposed site-specific risk-based criteria, which was confirmed with rebound confirmation testing. The SVE pilot study also indicated that chlorobenzene concentrations in groundwater coincidentally diminished below EPA Maximum Contaminant Levels (MCLs) since 2016 and 2018. The chemical constituents in subsurface soils and groundwater concentrations remaining in and around SWMU #11 are not anticipated to pose an unacceptable risk to human health or the environment with the current and future industrial/commercial use of the area.

SITE GEOLOGY AND HYDROGEOLOGY

The Facility is located on a relatively flat area within the coastal plain on the north coast of the island of Puerto Rico. The Facility is situated at an approximate elevation of 200 to 300 feet above sea level. The Manati River is the nearest body of water to the Facility, located about two miles to the east. The surface topography is controlled by a solution cavity, sinkhole collapse and fill, and is typical of a mature elevated karst platform. There are low hills on the

northern part of the Facility property, which are the result of the karst topography. Surface water drains into the sinkholes and into surface streams in the area. Numerous sinkholes are present in the area of the Facility and can be as large as 30 feet in diameter. The Facility has five permitted sinkholes that are used for stormwater drainage.

Lower Miocene-age Aymamon Limestone Formation is present at the surface of the Facility property. The formation is approximately 670 feet thick in some areas. The Aymamon Limestone Formation is composed of very fine to fine grained limestone, which locally may be coarsely fragmental and chalky. The formation is commonly thick-bedded and primarily composed of moderately fossiliferous and very pure (99%) calcium carbonate. Solution of the Aymamon Limestone typically develops a karst topography, which features mogotes (conical towers) and pepinos (steep-sided ridges) parallel to joint systems. The fracture patterns present in the Aymamon Limestone strike to the east-west and dip in a northeast direction. These fracture patterns are significant controlling factors in development of surface topography features and subsurface groundwater flow patterns.

There are three aquifers used for drinking water in the area, including a water-table aquifer and one artesian aquifers. The Aymamon Limestone is a water-table aquifer underlain by a confining unit that is part of the upper member of the Cibao Formation. The upper artesian aquifer is the Montebello and Qebrada Arenas Members of the Cibao Formation, and the lower artesian aquifer is the Lares Limestone. The water level in the water-table aquifer (Aymamon Limestone) ranges from 81 to 89 feet below ground surface (bgs). The water level in the upper artesian aquifer (Montebello and Qebrada Arenas), at depths of 900 and 957 feet, remains constant at 4.8 feet. In the lower artesian aquifer (Lares Limestone), at a depth of 1,898 feet, water levels range from 88 to 85 feet above ground surface. The potentiometric surface of both artesian aquifers is above ground level. Regional groundwater flow is to the north towards Caño Tiburones and Laguna Tortuguero.

SWMU #11 is underlain by a thick, karst limestone vadose-zone (approximately 290 feet to groundwater), with a soil (silt, sand, and clay-rich) filled sinkhole 10 to 80 feet deep. Bedrock is within 10 feet of the surface around most of SWMU #11, with the exception of the aforementioned sinkhole.

EXPOSURE PATHWAYS

Potentially complete exposures pathways for the Facility are described below:

- **Soil:** Direct contact, incidental ingestion, and inhalation of fugitive dust exposure pathways for future construction workers and current/future on-site commercial/industrial workers are potentially complete for VOCs. Twelve VOCs that were previously used at the Facility were detected in soil samples beneath SWMU #11, including benzene. The

nature and extent of VOC contamination in subsurface soils was delineated and there were no exceedances of RCRA action levels in soil. Exposure calculations using the maximum historical concentration of 23 milligrams per kilogram (mg/kg) of benzene indicate that potential excess lifetime cancer risks risk to future construction workers and current/future on-site commercial/industrial workers fall within or below the range of acceptable risks (1×10^{-4} to 1×10^{-6}) and the systemic toxicity hazard index for site related chemicals is not greater than 1.0. The exposure estimates produced for each receptor are conservative and likely overestimate the actual potential risk to future construction workers and current/future on-site commercial/industrial workers; therefore, the potential risk to these receptors from exposure to soil is anticipated to be within or below the EPA range of acceptable risks.

The Facility will continue to be used for pharmaceutical manufacturing; therefore, potential exposure pathways from VOCs in soil are limited or non-existent.

- **Soil Gas:** The inhalation exposure pathway for current/future on-site commercial/industrial workers is potentially complete. Risk based criteria were exceeded for current workers based on indoor air exposure to benzene. Specifically, benzene was detected in soil vapor above risk screening levels in an area proximal to SWMU #11. Following the SVE pilot study between 2015 and 2018, the source of benzene in soil vapor has been substantially diminished and the levels now meet the proposed site-specific risk-based criteria, confirmed with rebound confirmation testing. Currently, there are no occupied buildings in the area of SWMU #11. Additionally, there were no exceedances of the MCL for benzene in groundwater and there are no buildings currently above the area of the former contaminated groundwater plume; therefore, the potential exposure pathways from VOCs in soil gas are limited or non-existent.

- **Groundwater:** The direct contact and ingestion exposures pathways for current/future on-site commercial/industrial workers have been identified for chlorobenzene in groundwater. During the SVE pilot study, chlorobenzene was detected at concentrations exceeding the EPA MCL at two monitoring well locations (MW-1 and MW-2) between 2015 and 2016. Monitoring well MW-1, located within SWMU #11, produced a maximum chlorobenzene concentration of 0.45 milligrams per liter (mg/L), which exceeded the MCL of 0.1 mg/L. MCL exceedances in groundwater were delineated and were limited to a small plume in the vicinity of SWMU #11. Coincidental with continued SVE Pilot operations, chlorobenzene concentrations in groundwater continued to decline below the MCL and chlorobenzene was not detected in soil vapor samples. No VOCs, including chlorobenzene, have been detected in a nearby on-site production well. There are multiple drinking water wells in the area, including two wells at the Facility. One well is installed in the Aymamon water table aquifer at a depth of

approximately 500 feet bgs and the other well is installed in a deeper confined aquifer over an interval from 1,322 to 1,390 feet bgs. In general, groundwater is at a depth exceeding 200 feet below ground surface. Currently, no buildings exist above the area of the former contaminated groundwater plume; therefore, the potential exposure pathways from VOCs in groundwater and soil gas are limited or non-existent.

SELECTED REMEDY

The proposed remedial alternative for the Facility is No Further Action (NFA) with the establishment of institutional and/or administrative controls to prevent exposure of future construction workers, as well as current and future commercial/industrial workers to contaminated groundwater, soil and soil gas. Established zoning and deed restrictions will ensure the manufacturing area is restricted to its current industrial/commercial land use. The proposed deed restriction would identify the location of SWMU #11 to address the potential for future construction and provide notice that vapor barriers or controls may be warranted in the specific area of SWMU #11 in order to address the potential for a complete vapor intrusion exposure pathway. The deed restriction would also support the ultimate closure of the RCRA Part B Permit for the Facility.

INNOVATIVE TECHNOLOGIES CONSIDERED

NFA with the establishment of institutional and/or administrative controls was evaluated as a corrective action alternative to prevent exposure of future workers to contaminated groundwater, soil and soil gas. None of the alternatives evaluated for the Facility are considered innovative technologies.

PUBLIC PARTICIPATION

On May 24, 2021 a notice inviting the public to comment on the proposed remedy for the Facility was published by EPA in the *Primera Hora* newspaper. A 45-day public comment period on the proposed remedy was opened from May 24, 2021 to July 7, 2021. Interested persons or organizations can submit their written comments and/or request a virtual public hearing or meeting (referencing EPA Id. PRD090346909), to the following address:

Carmen Guerrero, Director
U.S. Environmental Protection Agency
Caribbean Environmental Protection Division
City View Plaza II, 48 CARR 165 STE 7000
Guaynabo, PR 00968-8073

The documents related to the investigations, interim corrective measures and remedy decision will be located on the following repositories:

Biblioteca Electrónica Sixto Escobar
Ave. Palmas Altas
Barceloneta, Puerto Rico 00617

Pfizer Pharmaceutical LLC
Barceloneta Facility
Route PR-2, Kilometer (Km) 58.2
Barceloneta, Puerto Rico

The decision documents and supporting references can be found at the Region 2 Corrective Action webpage: <https://www.epa.gov/hwcorrectiveactionsites/hazardous-waste-cleanup-pfizer-pharmaceuticals-llc-barceloneta-puerto-rico>.

Additional information regarding the Facility can be obtained from Luis Negrón, EPA Project Manager for the Site. The compliance history of former activities at the Site is also available at EPA, but may be subject to Freedom of Information Act (FOIA) requirements.

NEXT STEPS

Following approval of the selected remedy, EPA will work diligently with Pfizer representatives in order to monitor and ensure that current protections are maintained in the foreseeable future.

KEY WORDS:

Soil, soil gas, groundwater, risk, benzene, chlorobenzene, exposure, SWMU, land use, corrective measures, remedy decision, Puerto Rico, NFA, cancer risk, toxicity hazard, deed restriction, USEPA, CEPD, institutional control, Pfizer, Pfizer Pharmaceuticals, Barceloneta.

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