UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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DEC 14 2017

CERTIFIED MAIL/RETURN RECEIPT REQUESTED

William G. Gierke, P.G.
Senior Manager
Pfizer Inc.
100 Route 206 North, MS LLA-401
Peapack, NJ 07977

RE: EPA comments on the October 2017 Risk-Based Closure Criteria for Remedial Activities Technical Memorandum, Pfizer Pharmaceuticals LLC Carolina Site (EPA ID: PRD091197301)

Dear Mr. Gierke,

The U.S. Environmental Protection Agency (EPA) has reviewed the Risk-Based Closure Criteria (RBCC) for Remedial Activities Technical Memorandum (hereinafter RBCC Technical Memorandum) dated October 2017, and prepared by Golder Associates, for the former Pfizer Pharmaceuticals LLC Site located in Carolina, Puerto Rico. EPA has found that there are inconsistencies and deficiencies in the RBCC Technical Memorandum that need to be addressed before determining the document to be acceptable. Enclosed you will find our comments. If you have any questions regarding this matter, please feel free to contact David N. Cuevas, Lead Physical Scientist, at (787) 977-5856 or through electronic mail at cuevas.david@epa.gov.

Sincerely,

Carmen R. Guerrero Pérez, Director
Caribbean Environmental Protection Division

Enclosure

cc: Manuel Claudio Rodríguez, PR Environmental Quality Board

U.S. ENVIRONMENTAL PROTECTION AGENCY, REGION II
Clean Air and Sustainability Division
Sustainability and Multimedia Programs Branch
290 Broadway, 25th Floor
New York, New York 10007-1866

MEMORANDUM

DATE: November 29, 2017

SUBJECT: Comments on Pfizer Pharmaceuticals, LLC, Carolina, Puerto Rico Site – 65th Infantry Avenue, Km 9.7 Risk-Based Closure Criteria for Remedial Activities Technical Memorandum prepared by Golder, Associates dated October 13, 2017

TO: David Cuevas, Geologist
CEPD, Response and Remediation Branch, RCRA Team

FROM: Gina Ferreira, Environmental Scientist
CASD, Sustainability and Multimedia Programs Branch

Note To Project Manager

This technical comment memo provides a summary of the document listed above as well as general comments, specific comments, and recommendations for your review and consideration. If you have any questions or concerns about these comments, you can contact me in person or via email or telephone. When the final USEPA letter to the responsible party or their contractor is sent out, please send me an electronic or paper copy of it for my records.

Summary

This Technical Memorandum summarizes the risk-based closure criteria (RBCC) for the facility based on potential on-site exposures to constituents of concern under current conditions via the potential vapor intrusion pathway.

Chlorinated volatile organic compounds were detected in soil and groundwater at the site. In 2015, a remedial action was implemented including injection of an amendment to accelerate biodegradation of the VOCs with subsequent groundwater monitoring.

In 2012, Golder completed a screening level human health risk assessment. Since then, site conditions have changed, as constituent concentrations in soil and groundwater are significantly reduced and multiple buildings have been demolished. Pfizer requested that Golder evaluate current conditions at the site to establish RBCC that would be protective of human health. A multi-step approach was used to establish the RBCC including evaluating current data, selecting site-related COPCs, and analysis with predictive modeling.

Golder reviewed the groundwater data from 29 shallow monitoring wells and 36 injection wells. The following constituents were identified for groundwater: ethane, ethene, methane, 1,1-

dichloroethene, cis-1,2-dichloroethene, total 1,2-dichloroethene, tetrachloroethene (PCE), trichloroethene (TCE), and vinyl chloride. For soil, Golder reviewed the data from 32 soil borings. The following constituents were identified: chloroform, PCE, TCE, cis-1,2-dichloroethene, trans-1,2-dichloroethene, and vinyl chloride.

The USEPA vapor intrusion screening levels (VISLs) for commercial/industrial workers were used as the primary source for human health risk-based screening levels based on a target cancer risk of $1x10^{-6}$ and a target hazard quotient of 0.1, and a default groundwater to indoor air attenuation factor of 0.001. Constituents whose maximum concentrations in groundwater were reported above either their carcinogenic or non-carcinogenic VISL for groundwater were considered COPCs for which a constituent-specific RBCC would be derived. The results of this comparison identified three constituents (PCE, TCE, and vinyl chloride) as COPCs in groundwater. RBCC were not derived for five constituents in contaminated groundwater (cis-1,2-dichloroethene, total 1,2-dichloroethene, ethane, ethene, and methane), which lacked VISL values due to the lack of inhalation toxicity values. They were not retained as COPCs and were qualitatively evaluated in the uncertainty analysis.

Golder did not evaluate the vadose zone as a medium for the vapor intrusion pathway and, so did not propose RBCC for either soil or soil gas.

Golder modified the Johnson and Ettinger (J&E) model for vapor intrusion to reflect site-specific conditions and revised default values for groundwater temperature and soil properties. The 30 shallow monitoring wells were separated based on geographic location in order to evaluate potential RBCCs based on specific areas of the site, rather than on a single well location. The depth to groundwater for each well grouping was calculated by averaging the average depth to groundwater for each well within a group.

The lithology from the ground surface through the shallow saturated zone is primarily comprised of saprolite material. Golder contends that this soil type best corresponds to sandy clay in the J&E model and its default values were used in the J&E model. The average default groundwater temperature for south Florida of 25 degrees Celsius was used in the model which is close to what was observed at the site (27 degrees Celsius). The groundwater to indoor air attenuation factors for the COPCs are present in Table 3.

The RBCC were calculated on a constituent and monitoring well location grouping-specific basis using the site-specific groundwater attenuation factors, adjusted industrial worker RSLs for ambient air, and constituent-specific Henry's law constants. In order to account for cumulative risk in the calculation of the RBCC, the constituent-specific industrial worker RSLs for ambient air were adjusted to reflect a target cancer risk of 2×10^{-5} and target hazard quotient of 1.0 which is appropriate as PCE, TCE, and vinyl chloride have differing target organs.

Golder calculated the RBCC for each COPC within each of the eight monitoring well groups and used the lowest, most conservative, value for each COPC selected as the final site-wide RBCC. The site-wide RBCCs are: PCE = 23,585, TCE = 2,482, and vinyl chloride = 3,104 micrograms per liter (ug/L).

PCE and vinyl chloride concentrations in groundwater at the site have not exceeded their proposed RBCC concentrations since 2011. The highest concentrations of PCE and vinyl chloride detected at the site have been 133 and 2,570 ug/L, respectively. Since full scale remedial implementation, TCE concentrations are and have remained below the proposed RBCC in wells MW-13S, MW-16S, MW-17S, and MW-18S. Groundwater results have indicated TCE

concentrations above the RBCC in two locations on the site; INJ-36 and INJ-38. Remedial implementation is expected to decrease these concentrations further.

General Comments

The risk-based closure criteria presented in this technical memorandum "are based on potential on-site exposures to constituents of concern under current conditions via the potential vapor intrusion pathway" [underlining added for emphasis]. By contrast, the 2015 *OSWER Technical Guide For Assessing And Mitigating The Vapor Intrusion Pathway From Subsurface Vapor Sources To Indoor Air* ("OSWER VI Guide") recommends that "site managers also evaluate whether subsurface vapor sources that remain have the potential to pose unacceptable human health risks due to vapor intrusion in the future if site conditions were to change" [underlining added for emphasis]. If reasonably expected future land use includes residential use, then the risk-based closure criteria that would allow such future use should be based upon residential buildings and exposure factors, rather than commercial factors only. Proposed future land use of the facility needs to be fully researched and included in this technical memorandum in order to ensure that the risks to the proper future receptors are evaluated.

To more thoroughly evaluate the risk-based closure criteria, it would be useful to review in concert a summary of the scope of the Remedial Action Plan. Information on the types of institutional controls proposed, the lateral extent of groundwater that will be subject to the risk-based closure criteria, and the conceptual site model (e.g., What is the source of the known contamination? In what direction does groundwater flow and at what apparent velocity?) should be summarized in the introduction of the subject memorandum (Section 1.0 or 2.0), with appropriate citation to previous documents that contain more detailed information and would render the subject memorandum more useful as a stand-alone document.

Risk-based closure criteria are proposed only for groundwater. Risk-based closure criteria for soil are not proposed, in part because of the argument that the contaminated soils "are at a significant depth (> 20 ft bgs), which would limit any potential vapor intrusion risks" and "are likely to decrease as remedial activities continue." This rationale is ill-considered and ill-supported. This rationale is also in direct conflict with the appropriate decision to develop closure criteria for contaminated groundwater based upon a similar fact pattern (i.e., concentrations of vapor-forming chemicals in groundwater also are "at a significant depth" in some locations and are expected "to decrease as remedial activities continue"). Since soil contaminated with VOCs could act as a source to groundwater and indoor air, this medium needs to be addressed.

The OSWER VI Guide notes that "Specific factors that may result in relatively unattenuated or enhanced transport of vapors into a building include … very shallow groundwater sources (e.g., depths to water less than five feet below foundation level)." Golder appears (see, for example, page 2, Section 2.2.1) to have mis-represented/mis-interpreted this statement as indicating that groundwater quality data from shallow wells should not be used for purposes of identifying site-related chemicals of concern. Groundwater data from wells less than 5 feet below ground surface should be used to identify COCs for the vapor intrusion exposure pathway.

Golder used a 2004 version of the Johnson and Ettinger Model for Subsurface Vapor Intrusion into Buildings. A 2017 version of this model is available and should be used since it is the most current; it can be found at:
https://www.epa.gov/vaporintrusion/epa-spreadsheet-modeling-subsurface-vapor-intrusion

Golder/Pfizer should identify and justify suitable input values that yield conservative closure criteria, consistent with recommendations in the *OSWER Technical Guide For Assessing And Mitigating The Vapor Intrusion Pathway From Subsurface Vapor Sources To Indoor Air* (OSWER Publication 9200.2-154).

Risk-based closure criteria should be established for methane in soil gas, based upon its ability to pose an explosion hazard and to exert a demand for oxygen in the vadose zone, which otherwise might help support aerobic biodegradation of vinyl chloride.

Specific Comments

1. Page 2, Section 2.1, first bullet – Please indicate the groundwater depth considered "shallow" and provide some text indicating the minimum and maximum depth of all monitoring and injection wells sampled at the site.

2. Page 3, Section 2.2.2, 1st paragraph, last sentence – Please explain how the impacted soils "are likely to decrease as remedial activities continue at the site"?

3. Page 3, Section 3.0, 2nd paragraph – In order to be conservative in the modeling of soil gas intrusion, the shallowest depth from any well within a well grouping should be used as the depth to groundwater.

4. Page 4, 1st paragraph – There needs to be some justification and explanation provided as to why the saprolite material present at the site corresponds with the characteristics of sandy clay listed in the Johnson and Ettinger model.

5. Page 4, Section 4.0 – Industrial worker RSLs for ambient air should not be adjusted; they should be based on a target cancer risk level of 1.0×10^{-6} (not 2×10^{-5}) and a target hazard quotient of 1.0.

6. Page 6, 1st paragraph, last two sentences – In regards to the VOCs without inhalation toxicity values, what is the basis for stating that the "toxic effects from exposure to these compounds is thought to be less than those with available toxicity criteria"? Unless there is satisfactory (e.g., evidence-based) support, this claim should be considered unsupported and struck from the subject document.

7. Tables 1 and 2 – The 12th column title needs to be changed to state "Risk-Based Vapor Intrusion Screening Levels."

8. Table 3, Footnote 4 – Change the reference to Appendix C since it contains the relevant modeling information not Appendix A.

9. Table 3, Footnote 5 – The USEPA RSLs for industrial workers should not be adjusted; they should be based on a target cancer risk level of 1.0×10^{-6} and a target hazard quotient of 1.0.

10. Figure 1 – MW-29S appears to be missing from Figure 1.