DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION

Resource Conservation and Recovery Act (RCRA) Corrective Action
Environmental Indicator (EI) RCRAInfo code (CA750)
Migration of Contaminated Groundwater Under Control

Facility Name: Fenwal International, Inc.
Facility Address: ROAD 357 KM 0.8, MARICAO, PR 00606
Facility EPA ID#: PRD000706473

Definition of Environmental Indicators (for the RCRA Corrective Action)

Environmental Indicators (EI) are measures being used by the RCRA Corrective Action program to go beyond programmatic activity measures (e.g., reports received and approved, etc.) to track changes in the quality of the environment. The two EIs developed to-date indicate the quality of the environment in relation to current human exposures to contamination and the migration of contaminated groundwater. An EI for non-human (ecological) receptors is intended to be developed in the future.

Definition of "Migration of Contaminated Groundwater Under Control" EI (CA750)

A positive "Migration of Contaminated Groundwater Under Control" EI determination ("YE" status code) indicates that the migration of "contaminated" groundwater has stabilized, and that monitoring will be conducted to confirm that contaminated groundwater remains within the original "area of contaminated groundwater" (for all groundwater "contamination" subject to RCRA Corrective Action at or from the identified facility (i.e., site-wide)).

Relationship of EI to Final Remedies

While final remedies remain the long-term objectives of the RCRA Corrective Action program, the EIs are near-term objectives which are currently being used as program measures for the Government Performance and Results Act of 1993 (GPRA). The "Migration of Contaminated Groundwater Under Control" EI pertains ONLY to the physical migration (i.e., further spread) of contaminated groundwater and contaminants within groundwater (e.g., non-aqueous phase liquids or NAPLs). Achieving this EI does not substitute for achieving other stabilization or final remedy requirements and expectations associated with sources of contamination and the need to restore, wherever practicable, contaminated groundwater to be suitable for its designated current and future uses.

Duration / Applicability of EI Determinations

EI Determination status codes should remain in the Resource Conservation and Recovery Information System (RCRAInfo) national database ONLY as long as they remain true (i.e., RCRAInfo status codes must be changed when the regulatory authorities become aware of contrary information).

Facility Information

Fenwal International Inc. (hereinafter Fenwal) operates a medical devices manufacturing facility at two (2) properties owned by the Puerto Rico Industrial Development Company (PRIDCO), located at State Road PR-357, Km. 0.8, in the Municipality of Maricao, Puerto Rico (the Facility). The total surface area of the properties adds up to approximately 15.2 acres. The Facility includes two (2) main buildings with a total of approximately 100,000 square foot used for office, manufacturing, and related operations. The

Facility was operated by Travenol Laboratories, Inc., until July 22, 1987, when the operator became Baxter Healthcare Corp. of Puerto Rico. In the year 2007, TPG, a group of investors, bought the Fenwal Division from Baxter Healthcare Corporation and in 2012, Fresenius Kabi bought Fenwal International from TPG (Ref. 1). Manufacturing operations at the facility began in May 1972 and continue to this date (Ref.1, 2)

Back on 1980, the facility submitted to EPA the Part A Permit application and obtained Interim Status as a Treatment, Storage, and Disposal Facility (TSDF), under the Resource Conservation and Recovery Act (RCRA) Program (Ref. 2). According to RCRAinfo, the two (2) units under interim status were finally clean-closed in September 1986. Since 1996, the facility appears as a Small Quantity Generator (SQG). Currently, the facility still maintains their SQG classification (RCRAinfo).

1. Has **all** available relevant/significant information on known and reasonably suspected releases to the groundwater media, subject to RCRA Corrective Action (e.g., from Solid Waste Management Units (SWMU), Regulated Units (RU), and Areas of Concern (AOC)), been **considered** in this EI determination?

   X If yes - check here and continue with #2 below.

   ___ If no - re-evaluate existing data, or

   ___ If data are not available, skip to #8 and enter "IN" (more information needed) status code.

Summary of Solid Waste Management Units (SWMUs) and Areas of Concern (AOCs):

In 1988, the former Puerto Rico Environmental Quality Board (PREQB) conducted a RCRA Facility Assessment (RFA) and identified two (2) Solid Waste Management Units (SWMUs) and five (5) Areas of Concern (AOCs).

SWMU's:

SWMU-1	Hazardous Waste Containers Storage Area
SWMU-2	Neutralization Tank

AOC's:

AOC-1	Raw Material Storage Area
AOC-2	Flammable and Raw Material Storage Area
AOC-3	Chemical Laboratory
AOC-4	Underground Storage Tanks
AOC-5	Boiler Room

The 1988 RFA recommended a sampling visit only for AOC-2 referred to as a "Flammable and Raw Material Storage Area", located in the backyard of the north side of plant #2.

AOC-2 consisted of a steel building within a key-fenced area with a concrete floor with dimensions of 31' L X 20' W and surrounded by a curb 8" height X 6" wide, as described in the 1988 RFA. The physical description of AOC-2 has remained the same up to present day without any physical alteration. The description of AOC-2 contained in the 1988 RFA indicated that this area was used as a raw material storage area for Cyclohexanone, Methyl Ethyl Ketone, Isopropyl Alcohol, Chlorine and Dimethyl Chloride. AOC-2 was never used to store hazardous wastes. The AOC-2 is no longer used for the storage of flammable and the raw materials, but rather used for the storage of wooden pallets, PVC pipes, acrylic material, and galvanized tubes, which materials are to be used elsewhere in the Facility. At some point in time paper for recycling had also been stored inside AOC-2. The 1988 RFA indicted that during the visual site investigation some stains on the soil located beneath the drainage of AOC-2 were observed and recommended that further investigation of this area be conducted through sampling and analysis activities (Ref. 1, 2).

On December 2016, EPA issued a letter to Fenwal imposing a RCRA Facility Investigation (RFI), after finding that the recommendations made in the 1988 RFA regarding AOC-2 had not been addressed (Ref 3). After approval of the Work Plan by EPA on October 2019 (Ref. 4, 5), Fenwal conducted the RFI on June 2020 to determine presence, if any, of volatile organic compounds (VOCs), semivolatile organic

compounds (SVOCs) and non-halogenated organics in soil sampled from AOC-2 (Ref. 1). Results of the RFI show that no constituents of concern occur in soil media above applicable screening levels, for industrial soil, in the vicinity of AOC-2 (Ref. 1).

2. Is **groundwater** known or reasonably suspected to be "**contaminated**"[1] above appropriately protective "levels" (i.e., applicable promulgated standards, as well as other appropriate standards, guidelines, guidance, or criteria) from releases subject to RCRA Corrective Action, anywhere at, or from, the facility?

___ If yes - continue after identifying key contaminants, citing appropriate "levels," and referencing supporting documentation.

_X_ If no - skip to #8 and enter "YE" status code, after citing appropriate "levels," and referencing supporting documentation to demonstrate that groundwater is not "contaminated."

___ If unknown - skip to #8 and enter "IN" status code.

Rationale:

On June 2020, Fenwal conducted soil sampling as part of the RCRA Facility Investigation. Surface (0-2 ft) and subsurface (2-10 ft) soil samples were collected from borings adjacent to the to the four sides of the dike at AOC-2 and analyzed for VOCs, SVOCs and non-halogenated compounds. Results indicate soils adjacent to AOC-2 do not have constituents of concern above applicable screening levels for industrial soil. (Ref. 1). Given the results of the RFI, no groundwater contamination is expected and No Further Action (NFA) is necessary at the facility. On September 3, 2020, EPA concurred with Fenwal regarding the NFA determination for the facility (Ref. 6).

[1] "Contamination" and "contaminated" describes media containing contaminants (in any form, NAPL and/or dissolved, vapors, or solids, that are subject to RCRA) in concentrations in excess of appropriate "levels" (appropriate for the protection of the groundwater resource and its beneficial uses).

3. Has the **migration** of contaminated groundwater **stabilized** (such that contaminated groundwater is expected to remain within "existing area of contaminated groundwater"[2] as defined by the monitoring locations designated at the time of this determination)?

___ If yes - continue, after presenting or referencing the physical evidence (e.g., groundwater sampling/measurement/migration barrier data) and rationale why contaminated groundwater is expected to remain within the (horizontal or vertical) dimensions of the "existing area of groundwater contamination"[2].

___ If no (contaminated groundwater is observed or expected to migrate beyond the designated locations defining the "existing area of groundwater contamination"[2]) - skip to #8 and enter "NO" status code, after providing an explanation.

___ If unknown - skip to #8 and enter "IN" status code.

Rationale:

Not Applicable

[2] "Existing area of contaminated groundwater" is an area (with horizontal and vertical dimensions) that has been verifiably demonstrated to contain all relevant groundwater contamination for this determination, and is defined by designated (monitoring) locations proximate to the outer perimeter of "contamination" that can and will be sampled/tested in the future to physically verify that all "contaminated" groundwater remains within this area, and that the further migration of "contaminated" groundwater is not occurring. Reasonable allowances in the proximity of the monitoring locations are permissible to incorporate formal remedy decisions (i.e., including public participation) allowing a limited area for natural attenuation.

4. Does “contaminated” groundwater **discharge** into **surface water** bodies?

___ If yes - continue after identifying potentially affected surface water bodies.

___ If no - skip to #7 (and enter a “YE” status code in #8, if #7 = yes) after providing an explanation and/or referencing documentation supporting that groundwater “contamination” does not enter surface water bodies.

___ If unknown - skip to #8 and enter “IN” status code.

Rationale:

Not Applicable

5. Is the **discharge** of "contaminated" groundwater into surface water likely to be **"insignificant"** (i.e., the maximum concentration[3] of each contaminant discharging into surface water is less than 10 times their appropriate groundwater "level," and there are no other conditions (e.g., the nature, and number, of discharging contaminants, or environmental setting), which significantly increase the potential for unacceptable impacts to surface water, sediments, or ecosystems at these concentrations)?

___ If yes - skip to #7 (and enter "YE" status code in #8 if #7 = yes), after documenting: 1) the maximum known or reasonably suspected concentration[3] of key contaminants discharged above their groundwater "level," the value of the appropriate "level(s)," and if there is evidence that the concentrations are increasing; and 2) provide a statement of professional judgment/explanation (or reference documentation) supporting that the discharge of groundwater contaminants into the surface water is not anticipated to have unacceptable impacts to the receiving surface water, sediments, or ecosystem.

___ If no - (the discharge of "contaminated" groundwater into surface water is potentially significant) - continue after documenting: 1) the maximum known or reasonably suspected concentration[3] of each contaminant discharged above its groundwater "level," the value of the appropriate "level(s)," and if there is evidence that the concentrations are increasing; and 2) for any contaminants discharging into surface water in concentrations[3] greater than 100 times their appropriate groundwater "levels," the estimated total amount (mass in kg/yr) of each of these contaminants that are being discharged (loaded) into the surface water body (at the time of the determination), and identify if there is evidence that the amount of discharging contaminants is increasing.

___ If unknown - enter "IN" status code in #8.

Rationale:

Not Applicable

[3] As measured in groundwater prior to entry to the groundwater-surface water/sediment interaction (e.g., hyporheic) zone.

6. Can the **discharge** of "contaminated" groundwater into surface water be shown to be "**currently acceptable**" (i.e., not cause impacts to surface water, sediments or ecosystems that should not be allowed to continue until a final remedy decision can be made and implemented[4])?

___ If yes - continue after either: 1) identifying the Final Remedy decision incorporating these conditions, or other site-specific criteria (developed for the protection of the site's surface water, sediments, and ecosystems), and referencing supporting documentation demonstrating that these criteria are not exceeded by the discharging groundwater; OR 2) providing or referencing an interim-assessment[5], appropriate to the potential for impact, that shows the discharge of groundwater contaminants into the surface water is (in the opinion of a trained specialist, including an ecologist) adequately protective of receiving surface water, sediments, and ecosystems, until such time when a full assessment and final remedy decision can be made. Factors which should be considered in the interim-assessment (where appropriate to help identify the impact associated with discharging groundwater) include: surface water body size, flow, use/classification/habitats and contaminant loading limits, other sources of surface water/sediment contamination, surface water and sediment sample results and comparisons to available and appropriate surface water and sediment "levels," as well as any other factors, such as effects on ecological receptors (e.g., via bio-assays/benthic surveys or site-specific ecological Risk Assessments), that the overseeing regulatory agency would deem appropriate for making the EI determination.

___ If no - (the discharge of "contaminated" groundwater cannot be shown to be "**currently acceptable**") - skip to #8 and enter "NO" status code, after documenting the currently unacceptable impacts to the surface water body, sediments, and/or ecosystem.

___ If unknown - skip to 8 and enter "IN" status code.

Rationale:

Not Applicable

[4] Note, because areas of inflowing groundwater can be critical habitats (e.g., nurseries or thermal refugia) for many species, appropriate specialist (e.g., ecologist) should be included in management decisions that could eliminate these areas by significantly altering or reversing groundwater flow pathways near surface water bodies.

[5] The understanding of the impacts of contaminated groundwater discharges into surface water bodies is a rapidly developing field and reviewers are encouraged to look to the latest guidance for the appropriate methods and scale of demonstration to be reasonably certain that discharges are not causing currently unacceptable impacts to the surface waters, sediments or eco-systems.

7. Will groundwater **monitoring**/measurement data (and surface water/sediment/ecological data, as necessary) be collected in the future to verify that contaminated groundwater has remained within the horizontal (or vertical, as necessary) dimensions of the "existing area of contaminated groundwater?"

___ If yes - continue after providing or citing documentation for planned activities or future sampling/measurement events. Specifically identify the well/measurement locations which will be tested in the future to verify the expectation (identified in #3) that groundwater contamination will not be migrating horizontally (or vertically, as necessary) beyond the "existing area of groundwater contamination."

___ If no - enter "NO" status code in #8.

___ If unknown - enter "IN" status code in #8.

Rationale:

Not Applicable

8. Check the appropriate RCRAInfo status codes for the Migration of Contaminated Groundwater Under Control EI (event code CA750), and obtain Supervisor (or appropriate Manager) signature and date on the EI determination below (attach appropriate supporting documentation as well as a map of the facility).

_X_ YE - Yes, "Migration of Contaminated Groundwater Under Control" has been verified. Based on a review of the information contained in this EI determination, it has been determined that the "Migration of Contaminated Groundwater" is "Under Control" at the Fenwal International Inc. site, EPA ID# PRD000706473, located at in Maricao, Puerto Rico, under current and reasonably expected conditions. Specifically, this determination indicates that the migration of "contaminated" groundwater is under control. This determination will be re-evaluated when the Agency becomes aware of significant changes at the facility.

___ NO - Unacceptable migration of contaminated groundwater is observed or expected.

___ IN - More information is needed to make a determination.

Completed by: _____ Date: September 8, 2020

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Approved by: _____ Date: Sept. 22, 2020

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References:

1. Resource Conservation and Recovery Act Facility Investigation (RFI) Final Report, FENWAL International, Inc., Maricao, Puerto Rico. Prepared by UNIPRO Architects and Planners, LLP. August 2020.
2. RCRA Facility Assessment Report, Baxter Healthcare Corp. of Puerto Rico, Maricao, Puerto Rico, PRD000706473. Prepared by Puerto Rico Environmental Quality Board. August 1988.
3. Correspondence from Carmen R. Guerrero-Pérez, USEPA, to Ms. Joann Molina, Fenwal, Re: *Request of RCRA Facility Investigation*, Fenwal Kabi, Maricao, Puerto Rico. December 6, 2016
4. RCRA Facility Investigation Work Plan, Fenwal International Inc., Maricao, PR. September 16, 2019.
5. Correspondence from Carmen R. Guerrero-Pérez, USEPA, to Ms. Joann Molina, Fenwal, Re: *Approval of the September 2019 RCRA Facility Investigation Work Plan*, Fenwal International Inc., Maricao, PR. October 10, 2019.
6. Correspondence from Carmen R. Guerrero-Pérez, USEPA, to Ms. Joann Molina, Fenwal, *Approval of the August 2020 Final RCRA Facility Investigation Report*, Fenwal International, Inc., Maricao, Puerto Rico. September 3, 2020.

Locations where references may be found:

References reviewed to prepare this EI determination have been identified in the Facility Information section. Reference materials are available at U.S. EPA, Region 2.

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