

DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION

Resource Conservation and Recovery Act (RCRA) Corrective Action Environmental Indicator (EI) RCRAInfo Code (CA725) Current Human Exposures 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 (EIs) are measures being used by the RCRA Corrective Action program to go beyond programmatic activity measures (e.g., reports received and approved) 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 “Current Human Exposures Under Control” EI (CA725)

A positive “Current Human Exposures Under Control” EI determination (“YE” status code) indicates that there are no unacceptable human exposures to “contamination” (i.e., contaminants in concentrations in excess of appropriate risk-based levels) that can be reasonably expected under current land- and groundwater-use conditions (for all 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 “Current Human Exposures Under Control” EI is for reasonably expected human exposures under current land- and groundwater-use conditions ONLY and does not consider potential future land- or groundwater-use conditions or ecological receptors. The RCRA Corrective Action program’s overall mission to protect human health and the environment requires that final remedies address these issues (i.e., potential future human exposure scenarios, future land and groundwater uses, and ecological receptors).

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 soil, groundwater, surface water/sediments, and air, subject to RCRA Corrective Action (e.g., from solid waste management units (SWMUs), regulated units (RUs), and areas of concern (AOCs)), been **considered** in this EI determination?

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

If no - re-evaluate existing data, or

If data are not available skip to #6 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)^a 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. Are groundwater, soil, surface water, sediments, or air **media** known or reasonably suspected to be “contaminated”¹ above appropriately protective risk-based levels (applicable promulgated standards, as well as other appropriate standards, guidelines, guidance, or criteria) from releases subject to RCRA Corrective Action (from SWMUs, RUs or AOCs)?

Media	Yes	No	?	Rationale/Key Contaminants
Groundwater		X		Not sampled. See discussion below.
Air (indoors) ²		X		Not sampled. See discussion below.
Surface Soil (e.g., <2 ft)		X		Sampled. See discussion below.
Surface Water		X		Not sampled. See discussion below.
Sediment		X		Not sampled. See discussion below.
Subsurface Soil (e.g., >2 ft)		X		Sampled. See discussion below.
Air (Outdoor)		X		Not sampled. See discussion below.

X If no (for all media) - skip to #6, and enter YE, status code after providing or citing appropriate levels, and referencing sufficient supporting documentation demonstrating that these levels are not exceeded.

___ If yes (for any media) - continue after identifying key contaminants in each contaminated medium, citing appropriate levels (or provide an explanation for the determination that the medium could pose an unacceptable risk), and referencing supporting documentation.

___ If unknown (for any media) - skip to #6 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” describe media containing contaminants (in any form, NAPL and/or dissolved, vapors, or solids, that are subject to RCRA) in concentrations in excess of appropriately protective risk-based “levels” (for the media, that identify risks within the acceptable risk range).

² Recent evidence (from the Colorado Department of Public Health and Environment, and others) suggests that unacceptable indoor air concentrations are more common in structures above groundwater with volatile contaminants than previously believed. This is a rapidly developing field and reviewers are encouraged to look to the latest guidance for the appropriate methods and scale of demonstration necessary to be reasonably certain that indoor air (in structures located above (and adjacent to) groundwater with volatile contaminants) does not present unacceptable risks.

3. Are there **complete pathways** between “contamination” and human receptors such that exposures can be reasonably expected under the current (land- and groundwater-use) conditions?

Summary Exposure Pathway Evaluation Table
*Potential **Human Receptors** (Under Current Conditions)*

“Contaminated” Media	Residents	Workers	Day-Care	Construction	Trespasser	Recreation	Food ³
Groundwater	--	--	--	--	--	--	--
Air (indoor)	--	--	--	--	--	--	--
Surface Soil (e.g. < 2 ft)	--	--	--	--	--	--	--
Surface Water	--	--	--	--	--	--	--
Sediment	--	--	--	--	--	--	--
Subsurface Soil (e.g., > 2 ft)	--	--	--	--	--	--	--
Air (outdoors)	--	--	--	--	--	--	--

Instruction for Summary Exposure Pathway Evaluation Table:

1. Strike-out specific Media including Human Receptors’ spaces for Media which are not “contaminated” as identified in #2 above.
2. Enter “yes” or “no” for potential “completeness” under each “Contaminated” Media — Human Receptor combination (Pathway).

Note: In order to focus the evaluation to the most probable combinations some potential “Contaminated” Media - Human Receptor combinations (Pathways) do not have checked spaces. These spaces instead have dashes (“--”). While these combinations may not be probable in most situations they may be possible in some settings and should be added as necessary.

- If no (pathways are not complete for any contaminated media-receptor combination) - skip to #6, and enter “YE” status code, after explaining and/or referencing condition(s) in-place, whether natural or man-made, preventing a complete exposure pathway from each contaminated medium (e.g., use optional Pathway Evaluation Work Sheet to analyze major pathways).
- ___ If yes (pathways are complete for any “Contaminated” Media - Human Receptor combination) - continue after providing supporting explanation.
- ___ If unknown (for any “Contaminated” Media - Human Receptor combination) - skip to #6 and enter “IN” status code

Rationale:

Not Applicable

³ Indirect Pathway/Receptor (e.g., vegetables, fruits, crops, meat and dairy products, fish, shellfish)

4. Can the **exposures** from any of the complete pathways identified in #3 be reasonably expected to be **significant**⁴ (i.e., potentially “unacceptable”) because exposures can be reasonably expected to be: 1) greater in magnitude (intensity, frequency and/or duration) than assumed in the derivation of the acceptable “levels” (used to identify the “contamination”); or 2) the combination of exposure magnitude (perhaps even though low) and contaminant concentrations (which may be substantially above the acceptable “levels”) could result in greater than acceptable risks?

___ If no (exposures cannot be reasonably expected to be significant (i.e., potentially “unacceptable”) for any complete exposure pathway) - skip to #6 and enter “YE” status code after explaining and/or referencing documentation justifying why the exposures (from each of the complete pathways) to “contamination” (identified in #3) are not expected to be “significant.”

___ If yes (exposures could be reasonably expected to be “significant” (i.e., potentially “unacceptable”) for any complete exposure pathway) - continue after providing a description (of each potentially “unacceptable” exposure pathway) and explaining and/or referencing documentation justifying why the exposures (from each of the remaining complete pathways) to “contamination” (identified in #3) are not expected to be “significant.”

___ If unknown (for any complete pathway) - skip to #6 and enter “IN” status code.

Rationale:

Not Applicable

⁴ If there is any question on whether the identified exposures are “significant” (i.e., potentially “unacceptable”) consult a Human Health Risk Assessment specialist with appropriate education, training, and experience.

5. Can the “significant” **exposures** (identified in #4) be shown to be within acceptable limits?

_____ If yes (all “significant” exposures have been shown to be within acceptable limits) - continue and enter “YE” after summarizing and referencing documentation justifying why all “significant” exposures to “contamination” are within acceptable limits (e.g., a site-specific Human Health Risk Assessment).

_____ If no (there are current exposures that can be reasonably expected to be “unacceptable”) - continue and enter “NO” status code after providing a description of each potentially “unacceptable” exposure.

_____ If unknown (for any potentially “unacceptable” exposure) - continue and enter “IN” status code.

Rationale:

Not Applicable

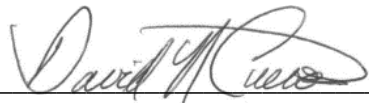
6. Check the appropriate RCRAInfo status codes for the Current Human Exposures Under Control EI event code (CA725), and obtain Supervisor (or appropriate Manager) signature and date on the EI determination below (and attach appropriate supporting documentation as well as a map of the facility):

YE - Yes, "Current Human Exposures Under Control" has been verified. Based on a review of the information contained in this EI Determination, "Current Human Exposures" are expected to be "Under Control" at the Fenwal International, Inc. site, EPA ID# PRD000706473, located at in Maricao, Puerto Rico, under current and reasonably expected conditions. This determination will be re-evaluated when the Agency/State becomes aware of significant changes at the facility.

NO - "Current Human Exposures" are NOT "Under Control."

IN - More information is needed to make a determination.

Completed by:



David N. Cuevas, Lead Physical Scientist
Response & Remediation Branch
Caribbean Environmental Protection Div.
EPA Region 2

Date: _____

Approved by:



Teresita Rodríguez, Chief
Response & Remediation Branch
Caribbean Environmental Protection Div.
EPA Region 2

Date: Sept. 22, 2020

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 under the Facility Information Section. Reference materials are available at U.S. EPA, Region 2.

Contact telephone and e-mail numbers: David Cuevas-Miranda
787-977-5856
Cuevas.David@epa.gov

FINAL NOTE: THE HUMAN EXPOSURES EI IS A QUALITATIVE SCREENING OF EXPOSURES AND THE DETERMINATIONS WITHIN THIS DOCUMENT SHOULD NOT BE USED AS THE SOLE BASIS FOR RESTRICTING THE SCOPE OF MORE DETAILED (E.G., SITE-SPECIFIC) ASSESSMENTS OF RISK.

^a The PREQB has merged into the Puerto Rico Department of Natural and Environmental Resources.