

DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION

RCRA Corrective Action Environmental Indicator (EI) RCRAInfo Code (CA750) Migration of Contaminated Groundwater Under Control

Facility Name: Lilly del Caribe, Inc.
Facility Address: Mayaguez, Puerto Rico
Facility EPA ID#: PRD091024786

Definition of Environmental Indicators (for the RCRA Corrective Action)

Environmental Indicators (EI) are measures being used by the Resource Conservation and Recovery Act (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 "Migration of Contaminated Groundwater Under Control" EI

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

The Lilly del Caribe, Inc. (Lilly del Caribe) facility covers approximately 45 acres in Mayaguez, Puerto Rico, and includes an administration building, maintenance shop and engineering building, warehouses, various process and manufacturing buildings, loading areas, a wastewater treatment plant, tank farm, drum storage area, and incinerator. Since 1966, the facility has manufactured a variety of bulk human

health pharmaceutical products. The surrounding property is mainly used for agricultural purposes (Ref. 2).

Materials involved in manufacturing include both organic- and inorganic-based compounds. The manufactured compounds result from various chemical and physical alterations to materials in batch-type operations, which are performed in a variety of tanks, and may involve several steps including heating, cooling, solvent extraction, distillation, filtration, crystallization, centrifugation, and drying (Ref. 2). The hazardous constituents that may be present in the waste streams produced at the facility are as follows: acetonitrile, acetophenone, benzene, carbon tetrachloride, chlorobenzene, chloroform, dibromoethane, ethylene dichloride, isobutyl alcohol, methylene chloride, phenol, pyridine, toluene, 1,1,1-trichloroethane, and 1,1,2-trichloroethane (Ref 1).

Hazardous wastes are stored and treated at the facility (Ref. 2). The facility submitted their RCRA Part A and Part B Permit Applications in July 1986 and March 1987, respectively (Ref. 1). A RCRA Facility Assessment (RFA) was completed for the facility in September 1987. A second RFA was completed in October 2000, followed by a Supplemental RFA in March 2003. According to the 2000 RFA, solid hazardous wastes are stored in a permitted hazardous waste storage area prior to transport offsite for treatment and disposal. Primary liquid wastes, which are mainly spent solvents, are capable of supporting autonomous combustion in an onsite incinerator's combustion chamber. Secondary liquid wastes, which are mainly water, are injected into the incinerator's combustion chamber for thermal destruction (Ref. 2).

In September 2004, a final RCRA Part B Permit was issued to the facility (this was a permit renewal); all solid waste management units and areas of concern that had been identified at the facility were listed as requiring no further corrective action (Ref. 4). On November 2008, Lilly ceased its incineration operations at Mayagüez.

References:

1. RCRA Facility Assessment, Draft Preliminary Assessment Report. Prepared by Ebasco Services, Inc. Dated September 1987.
2. RCRA Facility Assessment. Prepared by Puerto Rico Environmental Quality Board. Dated October 2000.
3. Supplemental RCRA Facility Assessment. Prepared by EPA. Dated March 2003.
4. Final RCRA Part B Permit. Dated September 2004.

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?

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 September 2004, a final RCRA Part B Permit was issued to the facility, and the following SWMUs and AOCs were identified (Ref. 4):

SWMU 1 – Wastewater Treatment Plant
SWMU 2 – Brule Liquid Waste Incinerator
SWMU 3 – Hazardous Waste Storage Tanks (12,000 gallon tanks)
SWMU 4 – Hazardous Waste Container Storage Area
SWMU 5 – Hazardous Waste Storage Tanks (50,000 gallon tanks)
SWMU 6 – Non-Hazardous Waste and Empty Drum Storage Area
SWMU 7 – Empty Drum Rinsing and Crushing Area
SWMU 8a – Crushed Drums Staging Area (Inactive; replaced by SWMU 8b in a new location)
SWMU 8b – Crushed Drums Staging Area
SWMU 9a – Wood Pallet Staging Area (Inactive; replaced by SWMU 9b in a new location)
SWMU 9b – Wood Pallet Staging Area
SWMU 10 – Used Batteries Staging Area
SWMU 11 – Recycling Material Area
SWMU 12 – Construction Debris/Soil Staging Areas
SWMU 13 – Spent Solvent Tanks for Outside Recovery
SWMU 14 – VIC Unit Condensate Tanks
SWMU 15 – Edward Unit Tank
SWMU 16 – Hazardous Waste Tank Trucks Loading and Unloading Area
SWMU 17 – Hazardous Waste Containers Loading and Unloading Area
SWMU 18a – South Process Waste Lift Station
SWMU 18b – North Process Waste Lift Station
SWMU 19 – Used Oil Accumulation/Storage Area
SWMU 20 – Asbestos for Offsite Disposal Accumulation Area
SWMU 21 – Hazardous Waste Generator Tanks
SWMU 22 – Callidus Liquid Incinerator
AOC 1 – Old Fire Training Area
AOC 2 – Fire Training Area
AOC 3 – Raw Material Tank Trucks Loading and Unloading Area
AOC 4 – Generator Building

No further action was recommended for all SWMUs and AOCs.

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:

No assessment of impacts to groundwater has been performed at the Lilly del Caribe facility; however, no evidence of releases at any SMWU or AOC was identified during the 2000 RFA and 2003 Supplemental RFA, with the exception of the South Process Waste Lift Station (SWMU 18a). According to the 2003 Supplemental RFA, a clear liquid with a solvent odor was observed in the concrete vault of this unit (Ref 3). According to the “Responsiveness Summary” for the 2004 RCRA Part B Permit, this occurrence was an isolated event and was promptly repaired; subsequent inspection of the concrete vault identified no cracks or deterioration (Ref. 4). Therefore, no further action was required. Based on review of the available file material, there are no known releases to groundwater from the facility.

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 concentration³ 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 eco-systems 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 concentration³ 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 concentration³ 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 concentrations³ 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 eco-systems that should not be allowed to continue until a final remedy decision can be made and implemented⁴)?

___ 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-assessment¹, 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 can not 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.

¹ 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

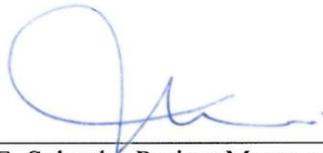
8. Check the appropriate RCRIS status codes for the Migration of Contaminated Groundwater Under Control EI (event code CA750), and obtain Supervisor (or appropriate Manager) signature and date on the EI determination below (attach appropriate supporting documentation as well as a map of the facility).

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 Lilly del Caribe site, EPA ID# PRD091024786, located in Mayaguez, Puerto Rico, under current and reasonably expected conditions. Specifically, this determination indicates that the migration of "contaminated" groundwater is under control, and that monitoring will be conducted to confirm that contaminated groundwater remains within the "existing area of contaminated groundwater." This determination will be re-evaluated when EPA 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.

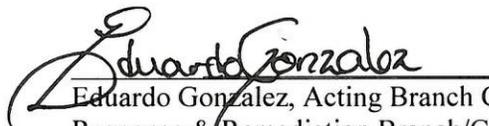
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Date: 3-21-12

Locations where references may be found:

References reviewed to prepare this EI determination are identified below. Reference materials are available at U.S. EPA, Region 2.

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