DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION

RCRA Corrective Action
Environmental Indicator (EI) RCRAInfo Code (CA725)
Current Human Exposures Under Control

Facility Name: Lilly del Caribe, Inc.
Facility Address: Mayaguez, Puerto Rico
Facility EPA ID No.: PRD091024786

Definition of Environmental Indicators (for the RCRA Corrective Action)

Environmental Indicators (EIs) 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 "Current Human Exposures Under Control" EI

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

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 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?

_X_ 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 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. 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		Not 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		Not 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:

No assessment of impacts to environmental media 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 environmental media from the facility.

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[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

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[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 RCRIS 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):

__X__ 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 Lilly del Caribe site, EPA ID# PRD091024786, located in Mayaguez, 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.

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.

Completed by: _____ Date: 3-16-2012
Angel E. Salgado, Project Manager
Response & Remediation Branch/CEPD
EPA Region 2

Reviewed by: Eduardo Gonzalez Date: 3/16/12
Eduardo Gonzalez, Acting Branch Chief
Response & Remediation Branch/CEPD
EPA Region 2

Approved by: _____ Date: 3-21-12
Jose Font, Acting Director
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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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