

US EPA ARCHIVE DOCUMENT

DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION

Interim Final 2/5/99

**RCRA Corrective Action
Environmental Indicator (EI) RCRIS code (CA725)****Current Human Exposures Under Control**

Facility Name: Eli Lilly and Company, Tippecanoe Laboratories
Facility Address: 1650 Lily Road Shadeland, IN 47905
Facility EPA ID #: IND 006 050 967

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 (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 #6 and enter "IN" (more information needed) status code.

BACKGROUND**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 EI 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 objective of the RCRA Corrective Action program the EI 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 are for reasonably expected human exposures under current land- and groundwater-use conditions ONLY, and do 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 Determinations status codes should remain in RCRIS national database ONLY as long as they remain true (i.e., RCRIS status codes must be changed when the regulatory authorities become aware of contrary information).

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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)?

	<u>Yes</u>	<u>No</u>	<u>?</u>	<u>Rationale / Key Contaminants</u>
Groundwater	x			acetone, benzene, toluene, chloroform, 1,2-DCA
Air (indoors) ²		x		
Surface Soil (e.g., <2 ft)		x		
Surface Water		x		
Sediment		x		
Subsurf. Soil (e.g., >2 ft)		x		
Air (outdoors)		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.

X 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 and Reference(s): Ground water beneath the main manufacturing area contains acetone (1 to 40 ppm range), benzene (around 40 ppm), chlorobenzene (about 0.5 ppm), chloroform (around 0.04 ppm), 1,2-DCA (about 1 ppm), methylene chloride (about 65 ppm), and toluene (around 0.05 ppm). The contaminated ground water is presently captured by extraction wells and a slurry wall-interceptor well system.

REFERENCES: T309/T310 Post Closure Ground Water Monitoring Reports, Eli Lilly & Co., 1992-2000. Quarterly Facility Ground Water Monitoring Reports, Harza Engineering Co., 1998-2000.

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 appropriately protective risk-based “levels” (for the media, that identify risks within the acceptable risk range).

² Recent evidence (from the Colorado Dept. of Public Health and Environment, and others) suggest 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.

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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	Trespassers	Recreation	Food ³
Groundwater	n	n	_n__	_n__			_n_
Air (indoors)			---				
Soil (surface, e.g., <2 ft)	---	---	---	---	---	---	---
Surface Water	---	---			---	---	---
Sediment	---	---			---	---	---
Soil (subsurface e.g., >2 ft)				---			---
Air (outdoors)	---	---	---	---	---		

Instructions 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 check spaces (“___”). While these combinations may not be probable in most situations they may be possible in some settings and should be added as necessary.

X 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 and Reference(s): Contaminated ground water is captured by extraction wells and an interceptor well - slurry wall system. REF. “Final Report for Seepage Collection and Contamination Mitigation”, Eli Lilly & Co., 1995; “T309/T310 Post-Closure Ground water Monitoring Reports”, Eli Lilly & Co., 1992-2000; Quarterly Ground Water Monitoring Reports, Harza Engineering Co., 1998-2000

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

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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 can not 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 and Reference(s):

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.

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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 and Reference(s):

Current Human Exposures Under Control
Environmental Indicator (EI) RCRIS code (CA725)

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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 Eli Lilly and Co., Tippecanoe Laboratories facility, EPA ID # IND 006 050 967, located at Shadeland, Indiana 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 (signature) _____ Date 10-10-00
 (print) Donald A. Heller
 (title) Environmental Scientist

Supervisor (signature) _____ Date 11-13-00
 (print) Hak K. Cho
 (title) Chief, Corrective Action Section
 (EPA Region or State) EPA Region 5

Locations where References may be found:

Final Report for Seepage Collection and Contaminant Mitigation, Eli Lilly & Co., 1995
T309/T310 Post Closure Ground Water Monitoring Reports, Eli Lilly & Co., 1992-2000
Quarterly Facility Ground Water Monitoring Reports, Harza Engineering Co., 1998-2000

Contact telephone and e-mail numbers

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(phone #) (312) 353-1248
(e-mail) Heller.Donald@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.

DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION

Interim Final 2/5/99

**RCRA Corrective Action
Environmental Indicator (EI) RCRIS code (CA750)****Migration of Contaminated Groundwater Under Control**

Facility Name: _____

Facility Address: _____

Facility EPA ID #: _____

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 #6 and enter "IN" (more information needed) status code.

BACKGROUND**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 EI 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 objective of the RCRA Corrective Action program the EI 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 ground water 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 Determinations status codes should remain in RCRIS national database ONLY as long as they remain true (i.e., RCRIS status codes must be changed when the regulatory authorities become aware of contrary information).

**Migration of Contaminated Groundwater Under Control
Environmental Indicator (EI) RCRIS code (CA750)**

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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.

_____ 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 and Reference(s):

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).

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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 and Reference(s):

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.

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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 and Reference(s):

Migration of Contaminated Groundwater Under Control
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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 judgement/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 eco-system.

_____ 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 and Reference(s):

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

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Environmental Indicator (EI) RCRIS code (CA750)

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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 eco-systems), 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 specialists, including ecologist) adequately protective of receiving surface water, sediments, and eco-systems, 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 eco-systems.

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

Rationale and Reference(s):

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.

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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 and Reference(s):

Migration of Contaminated Groundwater Under Control
Environmental Indicator (EI) RCRIS code (CA750)

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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 _____ facility, EPA ID # _____, located at _____. 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 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 _____ (signature) _____ Date _____
_____ (print) _____
_____ (title) _____

Supervisor _____ (signature) _____ Date _____
_____ (print) _____
_____ (title) _____
_____ (EPA Region or State) _____

Locations where References may be found:

Contact telephone and e-mail numbers

(name) _____
(phone #) _____
(e-mail) _____