

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: Boehringer Ingelheim Chemicals, Inc.
Facility Address: 2820 North Normandy Drive, Petersburg, VA 23805
Facility EPA ID #: VAD093561652

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?

- 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

The Beohringer Ingelheim, Inc. site is a 200 acre continued use facility located at 2820 North Normandy Dr. in Petersburg, Virginia. The facility is largely comprised of undeveloped forest areas with approximately 25 percent developed for production facilities and associated services including manufacturing buildings, process buildings, storage buildings, office space, parking lots, waste water treatment facilities, and landscaped areas. The Facility manufactures active pharmaceutical ingredients and intermediates for the pharmaceutical industry. Solid Waste Management Units (SWMUs) and Areas of Concern (AOCs) at the Facility include underground storage tanks, above ground storage tanks, components of the waste water treatment systems and associated piping, former hazardous waste storage area, and areas at which releases have been documented and/or cleaned up in the past.

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).

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

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		
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.
- 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:

The following is based on soil, soil gas, and groundwater analytical data that have been collected historically in support of environmental cleanup activities and the facility’s RCRA Facility Investigation (RFI) process including the conceptual site model and quantitative risk assessment. Historical cleanup activities occurred in association with closure of the former hazardous waste storage area (SWMU 3), cleanup of a broken sewer pipe discovered in 1995 (AOC 1), a toluene release (SWMU 16), and a manhole release from a hairline crack in 2008 (AOC 2). Soil and groundwater data collected during and subsequent to these cleanup activities indicate that the actions taken were appropriate and effective. Most notably, in response to the toluene release at SWMU 16, contaminated soil was removed and the excavation area was treated with ORC, an oxygen releasing compound, to accelerate the biodegradation of toluene in groundwater. Sample data from 2000 to 2004 indicate that toluene was effectively removed from soil and reduced in groundwater to below drinking water standards. Cleanup activities for AOC 1 and AOC 2 consisted of soil excavation and liquids removal. Subsequent groundwater sampling associated with these areas was conducted during the RFI process in support of developing the facility’s 2012 Conceptual Site Model (CSM). In addition, soil samples and groundwater samples associated with several SWMUs and AOCs site wide were collected during the RFI process in order to verify environmental conditions. In 2013, the facility completed their RFI process by conducting additional sampling in support of a quantitative risk assessment. Sample media included soil, soil gas, and groundwater. Sample locations targeted the areas with previously identified COPCs, based on exceedance of risk based Regional Screening Levels (RSLs).

Soil - RFI investigation results and previous cleanup results indicated that in 2011 methylene chloride was the only constituent in soil detected above industrial level human health regional screening levels (RSLs) for direct contact, which occurred in one subsurface soil sample located at AOC-1. 2013 confirmation soil sample results for several sampling depths at that location indicated that methylene chloride was not detected at a concentration above the residential RSL, indicating that methylene chloride in soil has attenuated and is no longer present.

Groundwater – Based on exceedances of drinking water standards (MCLs or tap water RSLs if an MCL is not available) in at least one sample, the constituents identified in groundwater during previous cleanups and the RFI investigation included barium, mercury, methylene chloride, Methyl Tertiary Butyl Ether (MTBE), and 1,2,3-trichlorobenzene. 2013

confirmation groundwater sample results for MTBE indicated that MTBE has attenuated but is still present at concentrations above its tap water RSL of 12 ug/L. Methylene chloride was detected above its MCL at AOC 1 in 2004, which was associated with the broken sewer pipe cleanup. 2013 confirmation groundwater sampling at AOC 1 verified that methylene chloride has attenuated to below its MCL of 5 ug/L. Barium and mercury were detected in groundwater at concentrations slightly higher than their respective MCLs in only one direct push grab sample, but are not considered representative or COPCs due to poor sample quality (turbidity) created by grab sampling methods using a direct push drill rig. Groundwater samples collected from properly constructed groundwater monitoring wells located within vicinity of the area indicated that barium and mercury were below drinking water standards. 1,2,3-trichlorobenzene was observed in only one sample in 2009 at an estimated concentration (0.69J ug/L) slightly above its RSL (0.52 ug/L), but was not observed elsewhere in facility groundwater.

In comparison to historical groundwater results, it appears that there are no longer any sources present at the facility and that constituents observed in groundwater have attenuated. Based on the most recent groundwater sampling results, there are no groundwater concentrations above MCL remaining at the site. The facility also conducted a quantitative risk assessment, included in the 2013 RFI Report, which demonstrated that groundwater is not contaminated above appropriately protective levels for current industrial and future unrestricted use. It concluded that the excess lifetime cancer risk (ELCR) is 3E-06 for an adult resident, 2E-06 for a child resident, and 6E-08 for adult site workers, which are at or below EPA's acceptable risk range of 1E-06 to 1E-04. It also concluded that the toxicity hazard indices (HI) for cumulative lifetime exposure to non-carcinogenic chemicals was 0.06 for an adult resident, 0.1 for a child resident, and 0.002 for an adult site worker, which are below EPA's target HI of 1.

Soil Gas – In 2013 the facility collected two soil gas samples from locations where MTBE and methylene chloride were observed. Results indicated that methylene chloride and MTBE were not detected in soil gas.

Based on the data for all sample media, the quantitative risk assessment presented in the 2013 RFI Report concluded that there are no unacceptable risks to human health or the environment under the current industrial use of the property or future unrestricted use.

Reference:

1. Conceptual Site Model Report by Arcadis, March 13, 2012
2. RCRA Facility Investigation Report by Arcadis, October 2013
3. Quantitative Risk Assessment, Section 7 RCRA Facility Investigation Report by Arcadis, October 2013

Footnotes:

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.

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

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)

<u>“Contaminated” Media</u>	Residents	Workers	Day-Care	Construction	Trespassers	Recreation	Food ³
Groundwater							
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.

- 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:

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

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

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:

Reference:

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.

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

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):

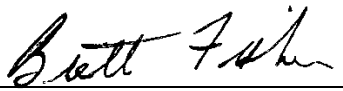
**Current Human Exposures Under Control
Environmental Indicator (EI) RCRIS code (CA725)**

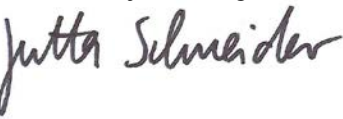
6. Check the appropriate RCRIS status codes for the Current Human Exposures Under Control EI (event code CA725), and obtain Supervisor (or appropriate Manager) signature and date on the EI determination below (attach appropriate supporting documentation as well as a map of the facility).

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 Boehringer Ingelheim Chemical, Inc. facility, EPA ID #VAD093561652, located at 2820 North Normandy Drive, Petersburg, VA 23805 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: 3-6-2014
(print) Brett Fisher, P.G.
(title) RCRA CA Project Manager

Supervisor (signature)  Date: 3-6-2014
(print) Jutta Schneider
(title) RCRA CA/GW Program Manager
(EPA Region or State) VDEQ

Locations where References may be found:

US EPA Region III
Land and Chemicals Division
1650 Arch Street
Philadelphia, PA 19103

Virginia Department of Environmental Quality
Office of Remediation Programs
629 East Main Street
Richmond, VA 23219

Contact telephone numbers and e-mail

(name) Mike Jacobi (EPA)
(phone #) 215-814-3435
(e-mail) Jacobi.mike@epa.gov

(name) Brett Fisher, P.G. (VDEQ)
(phone #) 804-698-4219
(e-mail) brett.fisher@deq.virginia.gov