AMERICAN INDUSTRIAL HEALTH COUNCIL

AIHC

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March 21, 1994

Mr. Harold F. Reheis
Director
Environmental Protection Division
Georgia Department of Natural Resources
205 Butler Street, S.E.
Suite 1154
Atlanta, Georgia 30334

Dear Mr. Reheis:

The American Industrial Health Council (AIHC) appreciates the opportunity to submit comments to the Environmental Protection Division (EPD) of the Georgia Department of Natural Resources on the draft Corrective Action Rule under the Georgia Hazardous Site Response Act. Because the timeframe for submitting these advance comments was brief, AIHC may choose to submit additional comments to EPD when the formal public comment period begins on April 1, 1994.

AIHC is a broad-based industry organization that advocates the use of sound scientific principles and procedures in the assessment and regulation of risks of chronic human health effects and directly related public policy issues. The Council's membership is a diverse coalition of companies and trade associations, including producers of consumer products, chemicals, foods, and beverages, high technology, pharmaceuticals, petroleum products, paper products, motor vehicles, aerospace and metals.

AIHC addresses only the generic science or science policy issues that serve as the foundation for major chronic health and regulatory policies. AIHC does not act as an advocate for any product or substance, although its generic positions directly affect the scope and impact of individual regulatory decisions.

While AIHC supports EPD's goal to establish cleanup standards based on health impact, chemical mobility, and environmental fate, it is important that the final standards be applied in a manner that considers site-specific circumstances and limitations. Furthermore, criteria for these standards must be based on sound science. AIHC urges EPD to reexamine its proposed risk reduction standards to ensure that Georgia's Corrective Action Rule is grounded in the best available science.

Please do not hesitate to contact me if you have questions.

Sincerely,

Nancy G. Doerrer
Deputy Director

Enclosures

Preliminary Comments on Georgia's Draft Corrective Action Rule
Proposed Rule 391-3-19

Below are preliminary comments focused on the use of risk assessment in the draft Corrective Action Rule. These comments will be expanded upon and added to during the public comment period.

- <u>General Comments Regarding the Risk Reduction Standards</u>
  AIHC supports EPD's goal of establishing cleanup standards based on health impact, chemical mobility, and environmental fate. It is important, however, that the final standards be applied in a manner that considers site-specific circumstances and limitations to the greatest extent possible, including technical feasibility and practicability.

  <u>Setting Different Standards Based on Land Use</u>
  Land use is an important concept in any risk assessment and used to evaluate current and future exposures. Realistic future land use scenarios should provide the basis for selection of controlling exposure scenarios/pathways. Development of cleanup criteria, whether generic or site specific values, should be based on future land use. Deed restrictions, as EPD has proposed, is one mechanism to ensure a site's continued land use designation. If a site can meet the Type 3 or 4 (non-residential use standards), no further action except for a deed notice is reasonable; however, the site should be removed from the HSI and not remain a Class IV site. If there is no adverse risk to human health or the environment based on site-specific conditions, including land use, then removal from the HSI is warranted.

  <u>Sources of Toxicity Data</u> AIHC would like to propose that facilities rely on (1) standard toxicological databases such as the Integrated Risk Information System (IRIS) and the Health Effects Assessment Summary Tables (HEAST); <u>and</u> (2) current, peer reviewed toxicological studies. The reliance on databases alone is questionable. First, the carcinogenicity assessment and reference doses contained in IRIS are often not based on the most current information and are not subject to peer review. Second, there is no external peer review of the methodologies used to derive the carcinogenicity assessments and reference doses. Finally, the expression of uncertainty inherent in the data included in IRIS is not sufficient.

  AIHC notes that EPA has recently acknowledged these limitations and concerns regarding IRIS and recognized that toxicological information other than that in IRIS may appropriately be considered under Superfund. (OSWER Dir. 9285.7-16, Dec. 21, 1993).

AIHC commends EPD for recognizing that the slope factors and reference doses reflect an absorption factor of 1. Actual absorption factors based on the specific form of the regulated substance should be incorporated into the risk equations for all risk reduction standards and not only Type 2 and 4 as proposed.

Use of a Site-Specific Risk Assessment - Although Type 2, and 4 (and 5) allow a departure from EPA "standard" exposure factors, there is essentially no provision in this rule for a site-specific risk assessment . A site-specific risk assesament entails much more than just being given the opportunity to adjust exposure factors. AIHC strongly urges the EPD to revise the language in the Type 2 and 4 cleanup goals from site specific exposure factors to site-specific risk assessment.

While site-specific risk assessments are tailored to accommodate differing factors and assumptions, all risk assessments have standard features (i.e., methodology) in common. The elements of a risk assessment include: hazard identification , toxicity assessment, exposure assessment and risk characterization (i.e., risk quantification and uncertainty analyses). Notably, a considerable amount of expertise is currently available in the area of exposure assessment such as the use of: probabilistic exposure assumption methods, fate and transport modeling; bioavailability, pharmocokinetics; etc.

The risk reduction standards also need to address the concept of "risk management", i.e., what does the risk estimate(s) actually mean in the overall remedial strategy, considering all factors.

Setting Target Risk and Hazard Index Levels Section 319-3-19-.07 (10) defines the cumulative target risks for carcinogens and hazard indices for systemic carcinogens. This language should apply to the Type 1 through 5 standards. Setting the level for cleanup goals at 10E-06 for Types 1-4 standards is contrary to current Superfund guidance.

The reliance upon a 10E-06 or 10E-05 risk target level for establishment of cleanup levels is contrary to current policy on risk assessment. In the 1990 National Contingency Plan, EPA rejected the 10E-06 risk target for carcinogens in favor of a risk range between 10E-04 and 10E-06. EPA guidance (OSWER Dir. 9355.0-30, April 22, 1991) further clarifies the EPA's general policy on risk levels as follows:

For sites where the cumulative site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 10E-04, action generally is not warranted.....Records of Decision for remedial actions taken at sites posing risks with the 10E-04 and 10E-06 risk range must explain why remedial action is warranted.

Use of Single-Point, Highly Conservative Exposure Factors
The use of single-point, highly conservative exposure factors to assess potential intakes is not reflective of sound science; nor is it consistent with state-of-the-art exposure evaluations. Default point estimate exposure factors create a worst-case scenario that is more extreme than any reasonable maximum exposure intended. The proposed standards should recognize that an upper-bound risk estimate is not a likely maximum estimate. AIHC recommends that appropriate distributions of all relevant exposure factors be combined in the best scientific manner to determine specific combinations of percentile concentration values, (e.g., 50th, 90th, or 95th percentile). Probabilistic determinations, "Monte Carlo" simulations, for example, can provide this type of analysis.

Use of the RAGS, Part B Equations AIHC requests that EPD give some more thought to the use of these equations in setting risk reduction standards. AIHC has specific concerns with the equations for residential versus non-residential soils and the combination of more than one exposure pathway (e.g., inhalation and ingestion) into one equation. Notably, EPD has chosen to apply RAGS equations 6 and 7 (combining inhalation and ingestion pathways) to residential scenarios which were originally intended for commercial/industrial standards. The RAGS equations 4 and 5 for residential soils look only at ingestion as the plausible exposure route. Also, EPA has proposed modifications to the RAGS, Part B 1991 equations in the *Draft Soil Screening Level Guidance* (September, 1993). AIHC would like to consider the technical merit of these modifications as well as examine other risk equations in place of those equations referenced in RAGS.

Use of Table 1, Appendix III (Groundwater Standards.) The reliance upon applicable, relevant, or appropriate requirements (ARARs) such as maximum contaminant levels (MCLs) for setting ground water medium-specific concentrations is inappropriate. MCLs are calculated maximum levels of contaminants for receptors that directly ingest water. However, groundwater must travel through the subsurface before contact with receptors and may be

significantly attenuated by this process, thus making the use of the MCL overprotective.

- <u>Specific Comments on Proposed Rule 931-3-19</u>

<u>Section 391-3-19-.06 Corrective Action</u>

(5) <u>Public Participation</u> - From a risk communication standpoint, it is essential that the results of any compliance report or risk assessment be presented clearly and in plain language along with a determination for corrective action based on set criteria. This approach would serve to ease public fear rather than arouse it. The public should and needs to be involved in the process. However, the determination of whether remediation is necessary based on human health or environmental impacts should not be left for a public meeting in an arena where participants may not have all the facts or may be misinformed.

<u>391-3-19-.07 Risk Reduction Standards</u>

(6) <u>Criteria for Type 1 Standards</u>
AIHC is strongly opposed to the approach that the point of compliance for groundwater be set at "all points that have been affected by the release" and for soil "all points above the water table that have been affected by the release." This approach gives no consideration to current or potential future receptors or exposure pathways. Points of compliance must be established to be protective of human health and the environment, taking into consideration site conditions and receptors.

(b) <u>Criteria for groundwater</u>. The requirement stating that, "if more than one regulated organic compound is present in groundwater, their sum shall not exceed 10 mg/L." is not based on good science. First, how to sum the groundwater concentrations is not addressed in the draft rule. A site could have negligible and discrete areas of groundwater contamination that when summed across a property could exceed 10 mg/L but present no adverse risk. Second, regardless of how the 10 mg/L is totaled, it is not based on a risk approach.

(c) <u>Criteria for soil.</u>
(1)(ii) Reword. "Demonstration through use of an approved analytical leaching procedure, such as the Toxicity Characteristic Leaching Procedure, SW-846 Method 1311 or other method approved by the EPD...."

(3) The target risk of 10E-06 is inappropriate (see general comment above).

(7) Criteria for Type 2 Standards
As previously stated in response to setting the points of compliance for the Type 1 standards, AIHC is strongly opposed to the approach taken that the point of compliance for groundwater be set at "all points that have been affected by the release" and for soil "all points above the water table that have been affected by the release." Points of compliance must be established to be protective of human health and the environment taking into consideration site conditions and receptors.

However, AIHC commends EPD on recognizing the importance of setting soil cleanup goals that are protective of groundwater cleanup goals and suggests rewording the point of compliance for soils is as follows:
(c)(1)" ..... at the point of exposure defined as the point at which groundwater could reasonably be used as a drinking water source, considering aquifer and land use."

(c)(3) same comment as 6(c)(3) above on target risk.

(8) Criteria for Type 3 Standards

(d)(1) The 1,000 ppm sum of volatilization (soil-to-air) standard is not based on good science. Henry's Law provides the air-water interfacial concentration which in no way is meant to represent ambient air concentrations. Mechanisms such as diffusion, dispersion and advection have been ignored.

(9) Criteria for Type 4 Standards

Criteria for groundwater. Additional sentence after "Within the property.....:." Alternatively, it must be demonstrated that Type 1 standards will not be exceeded at the property boundary through: fate and transport modeling, source control or source removal , or some combination thereof."

(10) General Considerations of Type 5 Standards
(h) Ground Water - EPD's conceptual approach to Type 5 ground water considerations is not based on the principles of risk assessment. The

requirement under section (h)(1) that, "cleanup levels shall be achieved throughout the plume of contaminated ground water..." should be deleted. Also "as long as vertical migration is eliminated" may be an impossibility -- especially in fractured bedrock.

Regarding section (h)(2), even if contaminated groundwater is hydraulically connected to a groundwater aquifer or surface water used for drinking water, the actual impact to potential receptors must be considered as part of the risk assessment process. This effort could be achieved through data collection, fate and transport modeling or a combination of each.