

US EPA ARCHIVE DOCUMENT

Methodology for Automated Level Comparison System to Support the Hazardous Waste Identification Rule (HWIR)

Background

The HWIR exemption, as currently envisioned, involves generator testing of hazardous wastes to determine whether concentrations of approximately 400 constituents are below established exit levels. EPA received numerous comments on the exit levels proposed in its December 1995 proposed rulemaking. These comments included statements that EPA failed to conduct a “reality check” on this set of exit levels, and that the levels are often more stringent than other regulatory programs, are less than natural background levels in soils, and are less than constituent levels found in common food items.

A major challenge EPA faces in conducting a “reality check” is the number of hazardous constituents which are included on the HWIR target analyte list. It is not a simple matter to inspect calculated exit levels to determine whether they are realistic, particularly when these levels are developed using scientific-based models. Nevertheless, the successful promulgation and implementation of HWIR will, in part, rely on stakeholder perception that the exit criteria are attainable. In fact, stakeholder confidence in EPA’s risk assessment efforts is linked, in part, to the “credibility” of the calculated exit levels.

EPA’s identified need is for an automated system that will allow quick and accurate comparisons of “lists” of constituents. With this system, EPA would have a tool to conduct a “reality check” on interim versions of newly calculated exit levels. EPA would also have a tool for gauging the significance of stakeholder concerns raised on the December 1995 proposal, responding to those concerns, and preparing a justification for the final version of exit levels selected for incorporation into HWIR.

Although EPA did not develop exit levels in time for the 1999 HWIR proposal, this automated level comparison system will be useful in future efforts to develop exit levels.

Automated Level Comparison System

Objective: The primary objective of the Automated Level Comparison System is to conduct a “reality check” on HWIR exit levels to:

- determine whether the HWIR exit levels may be overly conservative (e.g., below background soil levels)
- evaluate whether the HWIR exit levels may not be conservative enough (e.g., above acute toxicity levels)

- evaluate whether the HWIR exit levels are consistent with concentrations used by other regulatory programs (e.g., TC entry levels).

The conduct of these “reality checks” will involve a constituent by constituent comparison of HWIR exit levels with other constituent-specific values, for example, background soil levels, acute toxicity levels, TC entry levels, and other human benchmarks. The remainder of this methodology presentation refers to these various data sets as “comparative data sets.”

Strategy: The Automated Level Comparison System was designed using Microsoft Access, Version 2.0. A single data file contains a listing of the HWIR target analytes. This data file also contains constituent-specific information that would serve to fulfill the primary objectives noted above, and that would contain the recommended additional parameters.

Microsoft Access enables users to read/ browse the data file. Microsoft Access also allows users to conduct simple sorts of the data, for example, on a particular column of data (e.g., CAS number, constituent name). Users can open the data file (or sort the data file on any of the data fields) and scroll through to locate information on a particular constituent. Microsoft Access will also enable users to generate hardcopy reports..

In addition, the Microsoft Access format allows the easy addition of new data fields if new data sets, which would support the conduct of other “reality checks”, are later identified or selected.

Important Factors: Comparative Data Sets -- The Automated Level Comparison System contains numerous data sets (as identified later in this methodology presentation) that will be used to conduct constituent by constituent comparisons with the HWIR exit levels.

There is significant potential for misinterpretation of results based on the premises that underlie the collection of data for each data set. Care must be taken to not blindly interpret results. The purpose behind the data set must be considered. To the extent possible, such issues will be identified on the standard reports prepared for use with the Automated Level Comparison System.

The degree of quality within a data set is expected to be variable, particularly for the data sets that must be compiled from numerous references specifically for this effort. Variability can be attributed to, among other factors: different references supporting the data compilation

effort, levels reported in terms of maximum, median, or average levels, levels reported for studies conducted in different years across different timeframes, and levels reported for a wastewater matrix as opposed to a waste matrix.

The degree of completeness within a data set will also contribute to any comparative analysis conducted. Most comparative data sets will only partially “match” the HWIR target analytes. For example, the TC list of constituents is a set of forty levels. Background soil levels are available for metal constituents, and less available for organic constituents.

Reporting of Analysis Results -- Although the Automated Level Comparison System will simplify efforts to conduct various comparative analyses of the HWIR exit levels, the results of such analyses must be presented in a straightforward manner so that the analysis results can be easily used. Possible reports include:

- Which HWIR exit levels are above, below, or equal to other constituent levels
- Results sorted so that it is clear to what order of magnitude HWIR exit levels are different than other constituent levels. For example, the report may identify which constituents are 5 times, 10 times, 20 times, or 100 times other constituent levels
- To simply identify those constituents which have HWIR exit levels greater than 1 percent
- To simply identify those constituents for which analytical methods are available.

Data Fields: The data fields for the Automated Level Comparison System are designed with three objectives in mind. First, certain data fields will be included to maximize the quality of the actual data. With regard to the first objective, CAS numbers will be identified and included in the data file. Use of CAS numbers simplifies the challenges associated with constituent names, synonyms, and differing punctuation formats. In addition, electronic transfer of constituent lists or constituent-specific data used by other regulatory programs is often most easily accomplished through the use of CAS numbers. Suggested data fields of this type also include: a flag to identify whether the constituent is still considered to be an HWIR target analyte.

Second, certain data fields store the constituent-specific information necessary for EPA to conduct and report its comparisons. The Automated Level

Comparison System includes a data field specifying the chemical name most commonly used by EPA OSW efforts. The Automated Level Comparison System will also include the various comparative data sets of constituent levels.

Third, certain data fields will be included to expand upon the utility of the system for other applications. The continued development of HWIR will require access to constituent-specific information. For example, implementation aspects of HWIR rely on knowing whether analytical methods are available.

In summary, the suggested data fields include:

Constituent Names
CAS Numbers
Analytical Method Flag
Benchmark Values
HWIR Exit Levels
Comparative Data Sets (see next section)

Data Sources:

The ALCS includes the following datasets:

- CERCLA Guidance Soil Screening Levels (SSLs)
- EPA Region 3 Risk-Based Concentrations Guidelines
- FDA-Established Levels
- Food Background Levels
- Maximum Contaminant Levels (MCLs)
- POTW Effluent Data
- Universal Treatment Standards
- Toxicity Characteristic (TC) Levels
- Soil Background Levels
- Sewage Sludge Levels

Appendix A includes a full description of each dataset, the source of the information, and a description of limitations.

Appendix A: Automated Level Comparison System (ALCS) Data Sets

CERCLA Guidance Soil Screening Levels (SSLs)

The CERCLA Guidance Soil Screening Levels are risk-based concentrations derived from standardized equations combining exposure information assumptions with EPA toxicity data. Depending upon how the numbers will be used at the site and the amount of site-specific information that is collected or available, the Soil Screening Levels can range from generic soil screening levels to simple site-specific levels to site-specific Soil Screening Levels based on more detailed monitoring. The generic levels are based on a number of default assumptions chosen to be protective of human health for most site conditions and tend to be more stringent than site-specific levels.

The following Soil Screening Levels are included in the Automated Level Comparison System (ALCS):

	ALCS Code
• Ingestion of groundwater assuming no dilution or attenuation	SSL-GW1
• Ingestion of groundwater using a DAF of 20	SSL-GW20
• Direct ingestion of soil	SSL-Ingest
• Inhalation of soil particles	SSL-Inhal

Source: Soil Screening Levels Technical Background Document

- Use Limitations:
- Are guidelines, not regulatory standards.
 - May be “inaccurate” when contaminant concentrations approach the soil saturation limit.
 - Generic levels are conservative and likely to be protective for the majority of site conditions across the nation; however, these levels are not necessarily protective of all known human exposure pathways, reasonable land uses, or ecological threats.
 - Are established based on modeling assumptions that may differ from HWIR modeling assumptions.

EPA Region 3 Risk-Based Concentrations Guidelines

The Region 3 Risk-Based Guidelines are recommendations for conducting quantitative risk assessments for separate carcinogenic and non-carcinogenic chemical pathways. This guidance is intended to identify and focus on dominant contaminants of concern and exposure routes at the earliest feasible point in the baseline risk assessment. Use of the guidance postpones

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high-effort steps until later in the selection process and uses an absolute risk-based concentration screen, rather than a relative concentration toxicity screen.

The following concentration guidelines are included in the Automated Level Comparison System (ALCS):

	ALCS Code
• Ingestion of soil in industrial areas	Reg 3 Soil (Ind)
• Ingestion of soil in residential areas	Reg 3 Soil (Res)
• Ingestion of groundwater	Reg 3 SSL (GW)
• Ingestion of tap water	Reg 3 Tap Water

Source: The guidelines can be found at the EPA Internet address of <http://www.epa.gov/reg3hwmd/risk/>.

Use Limitations: - Are guidelines, not regulatory standards.
 - Are established based on modeling assumptions that may differ from HWIR modeling assumptions.

FDA-Established Levels

The Food and Drug Administration (FDA) establishes “action levels” for poisonous or deleterious substances to control levels of contaminants in human food and animal feed. Action levels and tolerances are established based on the avoid ability of the poisonous or deleterious substances and do not represent permissible levels of contamination where it is avoidable. Both action levels and tolerances represent limits at or above which FDA will take legal action to remove the product(s) from the market. Where no action level or tolerance exists, FDA may take legal action against the product at the minimal detectable level of the contaminant. Action levels are used as guidelines and are not enforceable standards; they are based on considerations of hazard only. Tolerances, on the other hand, are regulatory limits and are enforceable. Action levels are established and revised based on criteria specified in 21 CFR Parts 109 and 509 and are revoked when a regulation establishing a tolerance for the same substance and use becomes effective.

Source: Action levels are published in a document entitled the Compliance Policy Guides (CPG).

Use Limitations: - Action levels are guidelines, not regulatory standards.
 - Do not represent permissible or “safe” levels.

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Food Background Levels

Comments provided in response to EPA's 1995 HWIR proposal noted that HWIR exit levels for various constituents exceeded concentrations found in common food items and drinking water. This data is useful in evaluating whether common food items and drinking water would meet HWIR exit criteria. The following contaminants have "measured" values, based on the review of readily-available information:

- Acetone
- Aldrin
- Arsenic
- Benzene
- Beryllium
- Bis(2-ethylhexyl)phthalate
- Chlordane
- Chromium
- Copper
- DDE
- DDT
- Ethylene dibromide
- Fluoride
- Lindane
- Mercury
- Nickel
- Polychlorinated biphenyls (PCBs)
- Silver
- Zinc

Source: Eastman Chemical Co., Draft Comments on Various Benchmark Analyses, Draft February 5, 1996.

Friberg, et al., 1979. Handbook on the Toxicology of Metals.

National Research Council: Drinking Water and Health, 1977, 1980.

Sieler, H.G., and Sigal, H, eds. 1988. Handbook on Toxicity of Inorganic Compounds. [Fluoride]

U.S. EPA. [1980 and various dates]. Ambient Water Quality Criteria Documents.

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U.S. Department of Health and Humans Services, [various dates]. Toxicological Profile Documents.

- Use Limitations:
- Are based on studies that may be biased.
 - Are ultimately dependent on ingestion scenarios.

Maximum Contaminant Levels (MCLs)

Maximum Contaminant Levels are promulgated under the Safe Drinking Water Act (SWDA) of 1974, as amended in 1986, and consider technology and economic feasibility as well as health effects. For example, MCLs reflect the cost of treatment in public water systems, which is not relevant to human health risk. Finalized MCLs are used as the delisting levels for carcinogens and systematic toxicants, when available. Proposed MCLs are used as delisting levels for carcinogens and systematic toxicants when finalized MCLs are not available.

Source: 40 CFR Part 141, Subpart G

- Use Limitations:
- Are not solely risk-based.
 - Are available only for a limited set of constituents.
 - Must be compared to a waste extract concentration (for non wastewaters).

POTW Effluent Data

EPA conducted a study on 40 publicly-owned treatment works (POTWs) to characterize constituent concentrations in the influents to POTWs and POTW effluents. This data is useful in evaluating whether nonhazardous POTW influent and effluent wastewaters would meet HWIR exit criteria, and thus in determining whether industrial wastewaters should be held to a “higher” standard than non-industrial wastewaters.

Source: EPA’s Fate of Priority Pollutants in Publicly Owned Treatment Works, Final Report, Volume 1, EPA 440/1-82/303, September 1982.

- Use Limitations:
- Represent real-world data, not regulatory standards.

Sewage Sludge Levels

The Municipal Sewage Sludge Levels are regulatory standards which consist of general requirements, pollutant limits, management practices, and operational standards for the final use

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or disposal of sewage sludge applied to land, placed on a surface disposal site, or fired in a sewage sludge incinerator. The sewage sludge standards were established using data from EPA's National Sludge Survey Data; peer review reports generated for the proposed sludge standards by EPA's Land Practices Peer Review Committee and the EPA Science Advisory Board; EPA's "40 City Study" for constituent concentrations in municipal sludge; and other reports cited in 58 FR 9248 (e.g., EPA's Land Application and Distribution and Marketing of Sewage Sludge: Technical Support Document, 1989).

Source: 40 CFR Part 503

U.S. EPA, 1989. Peer Review - Standards for the Disposal of Sewage Sludge, U.S. EPA Proposed Rule, 40 CFR Parts 257 and 503.

U.S. EPA, 1989. Review of Proposed Sewage Sludge Incinerator Rules, 40 CFR Parts 257 and 503. EPA-SAB-EEC-89-035.

U.S. EPA, 1982. Fate of Priority Pollutants in Publicly Owned Treatment Works. Volume 1. Effluent Guidelines Division. Washington, DC. EPA 440/1-82-303.

Use Limitations: - Are available only for a limited set of constituents (i.e., inorganic constituents).
 - Are linked to certain management (i.e., application) requirements.
 - Are not solely risk-based concentrations. Concentrations, for example, are based on the sewage sludge survey conducted by EPA in 1988 and 1989 and represent the 99th percentile sludge concentration of information collected in that survey.
 - Are established, in part, on modeling assumptions that differ from HWIR modeling assumptions.

Soil Background Levels

Comments provided in response to EPA's 1995 HWIR proposal noted that HWIR exit levels for various constituents exceeded concentrations normally observed in soils. Numerous studies have been conducted to characterize constituent concentrations in soils, the most notable ones by the U.S. Geological Survey. This data is useful in evaluating whether soils would meet HWIR exit criteria.

Source: Shacklette, H.T. and Boerngen, J.G., 1984. Element Concentrations in Soils and Other Surficial Materials of the Conterminous United States. U.S. Geological Survey Professional Paper 1270.

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- Use Limitations:
- Metals are present in the environment as various compounds (e.g., oxides, nitrates, sulfides).
 - Chromium exists as two common valence states in environmental media, each which has a very different toxicological impact.
 - Metals may bioaccumulate and thus present greater exposure to ecological receptors.

Toxicity Characteristic (TC) Levels

The TC Levels are regulatory standards used to identify hazardous wastes that contain significant mobile concentrations of toxic constituents. A solid waste that generates an extract which contains any one or more of the TC constituents above the TC Levels is said to exhibit the characteristic of toxicity. TC Levels are used as “entrance” levels to identify wastes of concern and, therefore, present thresholds of concern

Source: 40 CFR 261.24, Table 1

- Use Limitations:
- Are based on MCLs and, therefore, are not solely risk-based.
 - Must be compared to a waste extract concentration (for non wastewaters).

Universal Treatment Standards

The Universal Treatment Standards contained in Phase II of the Land Disposal Restrictions Final Rule 40 CFR Parts 148, et al. (FR Vol. 59, No. 180) are a single set of requirements applying to most listed and characteristic hazardous wastes. The exceptions are TC wastes and a small number of wastes which have previously specified methods of treatments; for this latter category, the universal standards are an alternative. These standards eliminate differences in concentration limits for the same constituent in different wastes, setting a single standard for each constituent in its wastewater and non wastewater form. The economic based standards were established to simplify compliance by improving efficiency for reporting facilities and enforcement officials alike.

The following concentration guidelines are included in the Automated Level Comparison System (ALCS)

	ALCS Code
<ul style="list-style-type: none"> • Total concentration in non wastewaters 	UTS_NWW

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- Leachable concentration in non wastewaters UTS_NWWL
- Total concentration in wastewaters UTS_WW

Source: 40 CFR Section 268.48, Table UTS

Use Limitations: - Are technology-based, not risk-based.