other ecological receptors, and to the regulation of certain constituents that could potentially result in environmental consequences that go significantly beyond the bounds of a current waste management unit.

G. Background Concentrations in Soils and Other Issues Relating to Results

EPA has compared the exit levels for nonwastewaters to data on the variation in mean background concentrations found in soils. For some metals, the exit levels calculated based on risks at land application units are below ⁴ mean soil concentrations. One reason exit criteria may be below soil concentrations is that these metals bioaccumulate, causing greater exposure for higher trophic levels. Also, the acceptable levels for some of the metals that would be calculated for practices other than land application are significantly higher and not below mean soil concentrations.

If the final exit levels are below typical soil levels, EPA would consider promulgating levels based on concentrations that are either typical soil concentrations (national mean levels) or some percentile or portion of the naturally-occurring range such as the 10th percentile. If the effect of concern is an ecological impact, the rationale for using the 10th percentile (or similar figure if the data available does not allow that precision) would be that in 90 percent of locations, if the soil already contains those or greater levels, the ecological receptors existing in the area should already reflect the toxicity of the waste material; the rational for using the 10th percentile (or similar value) value is that human behavioral practices (e.g., treatment of groundwater prior to use) may already reflect protection from the potential toxicity of concern. EPA asks for comment on whether these are reasonable arguments.

EPA is concerned, however, that there are also issues of the chemical and physical form in which compound or chemicals exist, in both natural conditions and in the waste and that a simple comparison of total concentrations in soils and in wastes might be misleading about potential ecological or human impacts. EPA requests comment on these issues. EPA's first preference will be to reexamine the risk modeling to identify any inappropriate assumptions or modeling issues that may explain the low proposed exit level, and to look more carefully at those constituents where this issue only arises from the

modeling of risks from land application units, to identify potential contingent management solutions to this problem.

Finally, EPA requests comment on whether these arguments could be extended to site-specific determinations where information on local background constituent concentrations and form in soil are available and have been reviewed by a State regulatory authority. EPA assumes that such an approach would only apply if the background concentrations were more than very localized and the concentrations were naturally-occurring rather than due to past contamination. If a site-specific determination were adopted, two approaches are available that have been used in other contexts. One statistical technique for determining whether background data conform to a normal distribution assumption includes combining the Student-t difference of means test, presented in the Permit Guidance Manual on Unsaturated Zone Monitoring for Hazardous Waste Land Treatment Units, (EPA, 1986) with the normal tolerance interval approach found in Statistical Analysis of Ground Water at RCRA Facilities-Interim Final Guidance, (EPA, April 1989). The Student-t test compares averaged waste/ media concentrations to background concentrations, and is used to determine if the waste/media as a whole is within a specified criteria. However, even if the waste/media passes the Student-t test, individual sample concentrations may still exceed the tolerance interval limit. The normal tolerance interval approach is used to compare sample concentrations to an upper tolerance value based on the background mean, standard deviation, and sample size.

If such an approach is incorporated into the final rule, it would include criteria for defining and collecting adequate background samples. More specifically, the facility would be required to identify background locations, sample size, soil depth, etc. for at least four samples in a "difference of means" demonstration, and six to eight samples for a "tolerance of means" demonstration. The facility would also need to demonstrate the normalcy of the sample distribution. The Agency would require that this information be included as part of the facility's sampling and analysis plan and subject to review by the appropriate overseeing authority.

A more simplified approach would be to establish exit levels at ¹/₁₀ of the naturally occurring background level. The rationale for using ¹/₁₀ is that these levels would not appreciably contribute to the overall risk posed by elevated levels in the environmental media. EPA requests comment of this approach as well as the rationale.

Alternatively, the rule could defer any background level demonstrations to an omnibus authority for the overseeing agency. Under this concept, a claimant could submit information on naturally occurring background level and a request for modified exit levels to the agency overseeing the exemption process, which would have discretion to grant modifications where they are clearly justified. Comment is requested on the need for this authority.

The Agency solicits comments on other appropriate and generic ways (1) to identify background levels in soils, and (2) to incorporate the existing 40 CFR part 264, subpart F standards for establishing background levels for groundwater. Other suggestions that address the Agency's intent to promulgate a simplified exemption with little reliance on site-specific considerations but also allow for consideration of elevated background levels will be considered.

EPA also observed that some of the exit levels for organic chemicals appear relatively high (see, for example, the level for xylene). EPA believes that these results occurred primarily because these chemicals either are toxic only at relatively high concentrations or undergo high dilution during transport. EPA, however, requests comment on whether these chemicals are frequently co-disposed and, if so, whether they might pose cumulative risks not assessed by the risk analysis. EPA is interested in information on issues such as whether a waste containing one or more of these constituents at concentrations near exit levels would be ignitable or threaten the integrity of control measures such as liners.

H. Constituents with Extrapolated Riskbased Levels

EPA was unable to conduct the risk assessment for 187 of the 376 constituents on the exit list. In most of these cases, EPA was unable to find acceptable human health benchmarks to serve as the starting place for the assessment. In a few cases, EPA could not find values for critical physical or chemical properties, such as log K_{ow}s. Based on its past experience, EPA believes it would need at least a year to develop a new human health benchmark value for any constituent. EPA has less experience with the type of research and peer review needed to develop values for physical and chemical properties, but it believes that this process also would be timeconsuming.

⁴When compared with mean soil background levels provided by the USGS, the exit levels are not more that 1 order of magnitude more restrictive.