

generally be considered to be without appreciable risk of adverse health effects.

The EPA requests comment on using the "default percentage" approach and on setting the default hazard index limit at 0.2. The EPA is also requesting comment on whether an alternative HI limit, in some multiple of one, would be a more appropriate applicability cutoff.

A third option is to use available data (from scientific literature or EPA studies, for example) to determine background concentrations of HAP, possibly on a national or regional basis. These data would be used to estimate the exposures to HAP from non-PCWP sources in the vicinity of an individual facility. For example, the EPA's National-Scale Air Toxics Assessment (NATA)⁶ and ATSDR's Toxicological Profiles⁷ contain information about background concentrations of some HAP in the atmosphere and other media. The combined exposures from PCWP sources and from other sources (as determined from the literature or studies) would then not be allowed to exceed a hazard index limit of one. The EPA requests comment on the appropriateness of setting the hazard index limit at one for such an analysis.

A fourth option is to allow facilities to estimate or measure their own facility-specific background HAP concentrations for use in their analysis. With regard to the third and fourth options, the EPA requests comment on how these analyses could be structured. Specifically, EPA requests comment on how the analyses should take into account background exposure levels from air, water, food and soil encountered by the individuals exposed to PCWP emissions. In addition, we request comment on how such analyses should account for potential increases in exposures due to the use of a new or the increased use of a previously emitted HAP, or the effect of other nearby sources that release HAP.

The EPA requests comment on the feasibility and scientific validity of each of these or other approaches. Finally, EPA requests comment on how we should implement the section 112(d)(4) applicability cutoffs, including appropriate mechanisms for applying cutoffs to individual facilities. For example, would the title V permit process provide an appropriate mechanism?

Tiered analytical approach for predicting exposure. Establishing that a facility meets the cutoffs under section 112(d)(4) will necessarily involve

combining estimates of pollutant emissions with air dispersion modeling to predict exposures. The EPA envisions that we would promote a tiered analytical approach for these determinations. A tiered analysis involves making successive refinements in modeling methodologies and input data to derive successively less conservative, more realistic estimates of pollutant concentrations in air and estimates of risk.

As a first tier of analysis, EPA could develop a series of simple look-up tables based on the results of air dispersion modeling conducted using conservative input assumptions. By specifying a limited number of input parameters, such as stack height, distance to property line, and emission rate, a facility could use these look-up tables to easily determine whether the emissions from their sources might cause a hazard index limit to be exceeded.

A facility that does not pass this initial conservative screening analysis could implement increasingly more site-specific but more resource-intensive tiers of analysis using EPA-approved modeling procedures in an attempt to demonstrate that exposure to emissions from the facility does not exceed the hazard index limit. The EPA's guidance could provide the basis for conducting such a tiered analysis.⁸

The EPA requests comment on methods for constructing and implementing a tiered analytical approach for determining applicability of the section 112(d)(4) criterion to specific PCWP sources. It is also possible that ambient monitoring data could be used to supplement or supplant the tiered modeling approach described above. It is envisioned that the appropriate monitoring to support such a determination could be extensive. The EPA requests comment on the appropriate use of monitoring in the determinations described above.

Accounting for dose-response relationships. In the past, EPA routinely treated carcinogens as non-threshold pollutants. The EPA recognizes that advances in risk assessment science and policy may affect the way EPA differentiates between threshold and non-threshold HAP. The EPA's Draft Revised Guidelines for Carcinogen Risk Assessment⁹ suggest that carcinogens

be assigned non-linear dose-response relationships where data warrant. Moreover, it is possible that dose-response curves for some pollutants may reach zero risk at a dose greater than zero, creating a threshold for carcinogenic effects. It is possible that future evaluations of the carcinogens emitted by this source category would determine that one or more of the carcinogens in the category is a threshold carcinogen or is a carcinogen that exhibits a non-linear dose-response relationship but does not have a threshold.

The dose-response assessments for formaldehyde and acetaldehyde are currently undergoing revision by the EPA. As part of this revision effort, EPA is evaluating formaldehyde and acetaldehyde as potential non-linear carcinogens. The revised dose-response assessments will be subject to review by the EPA Science Advisory Board, followed by full consensus review, before adoption into the EPA IRIS. At this time, EPA estimates that the consensus review will be completed by the end of 2003. The revision of the dose-response assessments could affect the potency factors of these HAP, as well as their status as threshold or non-threshold pollutants. At this time, the outcome is not known. In addition to the current reassessment by EPA, there have been several reassessments of the toxicity and carcinogenicity of formaldehyde in recent years, including work by the World Health Organization and the Canadian Ministry of Health.

The EPA requests comment on how we should consider the state of the science as it relates to the treatment of threshold pollutants when making determinations under section 112(d)(4). In addition, EPA requests comment on whether there is a level of emissions of a non-threshold carcinogenic HAP (e.g., benzene, methylene chloride) at which it would be appropriate to allow a facility to use the approaches discussed in this section.

Risk assessment results. The results of the human health risk assessments described below are based on approaches for quantifying exposure, risk, and cancer incidence that carry significant assumptions, uncertainties, and limitations. For example, in conducting these types of analyses, there are typically many uncertainties regarding dose-response functions, levels of exposure, exposed populations, air quality modeling applications, emission levels, and control effectiveness. Because the estimates derived from the various scoping approaches are necessarily rough, we are concerned that they not convey a

⁸ "A Tiered Modeling Approach for Assessing the Risks due to Sources of Hazardous Air Pollutants." EPA-450/4-92-001. David E. Guinnup, Office of Air Quality Planning and Standards, USEPA, March 1992.

⁹ "Draft Revised Guidelines for Carcinogen Risk Assessment." NCEA-F-0644. USEPA, Risk Assessment Forum, July 1999, pp 3-9ff. http://www.epa.gov/ncea/raf/pdfs/cancer_gls.pdf

⁶ See <http://www.epa.gov/ttn/atw/nata>.

⁷ See <http://www.atsdr.cdc.gov/toxpro2.html>.