

advances in risk assessment science and policy may affect the way EPA differentiates between threshold and nonthreshold HAP. The EPA's draft 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 Integrated Risk Information System. 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 nonthreshold 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 CAA section 112(d)(4). In addition, EPA requests comment on whether there is a level of emissions of a nonthreshold 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.

If the CAA section 112(d)(4) approach were adopted, the proposed rulemaking would likely indicate that the requirements of the rule do not apply to

any source that demonstrates, based on a tiered approach that includes EPA-approved modeling of the affected source's emissions, that the anticipated HAP exposures do not exceed the specified hazard index limit.

3. Applicability Cutoffs From Hydrogen Chloride Controls Under CAA Section 112(d)(4) of the CAA

This approach is an applicability cutoff for the threshold pollutant hydrogen chloride that is based on EPA's authority under CAA section 112(d)(4). Industry's suggested approach interprets this provision to allow EPA to exempt, from the hydrogen chloride controls, individual facilities that can demonstrate that their emissions of hydrogen chloride will not result in air concentrations above the inhalation reference concentration for hydrogen chloride, even if the category is otherwise subject to MACT.

If this approach were adopted, the proposed rulemaking would likely indicate that the requirements of the rule pertaining to hydrochloric acid do not apply to any source that demonstrates, based on EPA-approved modeling of the affected source's emissions, that the anticipated hydrochloric acid exposures do not exceed the inhalation reference concentration for hydrochloric acid.

4. Subcategory Delisting Under Section 112(c)(9)(B) of the CAA

The EPA is authorized to establish categories and subcategories of sources, as appropriate, pursuant to CAA section 112(c)(1), in order to facilitate the development of MACT standards consistent with section 112 of the CAA. Further, CAA section 112(c)(9)(B) allows EPA to delete a category (or subcategory) from the list of major sources for which MACT standards are to be developed when the following can be demonstrated: (1) In the case of carcinogenic pollutants, that "no source in the category * * * emits (carcinogenic) air pollutants in quantities which may cause a lifetime risk of cancer greater than one in one million to the individual in the population who is most exposed to emissions of such pollutants from the source"; (2) in the case of pollutants that cause adverse noncancer health effects, that "emissions from no source in the category or subcategory * * * exceed a level which is adequate to protect public health with an ample margin of safety"; and (3) in the case of pollutants that cause adverse environmental effects, that "no adverse environmental effect will result from emissions from any source."

Given these authorities and the suggestions from the white paper prepared by industry representatives (see docket number OAR-2002-0058), EPA is considering whether it would be possible to establish a subcategory of facilities within the larger industrial boiler and process heater source category that would meet the risk-based criteria for delisting. Such criteria would likely include the same requirements as described previously for the second scenario under the CAA section 112(d)(4) approach, whereby a facility would be in the low-risk subcategory if its emissions of threshold pollutants do not result in exposures which exceed the HI limits and if its emissions of nonthreshold pollutants do not result in exposures which exceed a cancer risk level of 10^{-6} . The EPA requests comment on what an appropriate HI limit would be for a determination that a facility be included in the low-risk subcategory.

Since each facility in such a subcategory would be a low-risk facility (i.e., if each met these criteria), the subcategory could be delisted in accordance with CAA section 112(c)(9), thereby limiting the costs and impacts of the proposed rule to only those facilities that do not qualify for subcategorization and delisting.

Facilities seeking to be included in the delisted subcategory would be responsible for providing all data required to determine whether they are eligible for inclusion. Facilities that could not demonstrate that they are eligible to be included in the low-risk subcategory would be subject to MACT and possible future residual risk standards. The EPA solicits comment on implementing a risk-based approach for establishing subcategories of industrial boiler and process heater facilities.

Establishing that a facility qualifies for the low-risk subcategory under CAA section 112(c)(9) will necessarily involve combining estimates of pollutant emissions with air dispersion modeling to predict exposures. The EPA envisions that we would employ the same tiered analytical approach described earlier in the CAA section 112(d)(4) discussion for these determinations.

One concern that EPA has with respect to this CAA section 112(c)(9) approach is the effect that it could have on the MACT floors. If many of the facilities in the low-risk subcategory are well-controlled, that could make the MACT floor less stringent for the remaining facilities. One approach that has been suggested to mitigate this effect would be to establish the MACT floor now based on controls in place for the

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.