Message

From: Dunton, Cheryl [Dunton.Cheryl@epa.gov]
Sent: 4/27/2020 11:50:27 AM
To: Dunn, Alexandra [dunn.alexandra@epa.gov]; Fischer, David [Fischer.David@epa.gov]; Tyler, Tom [Tyler.Tom@epa.gov]; Siciliano, CarolAnn [Siciliano.CarolAnn@epa.gov]; Dennis, Allison [Dennis.Allison@epa.gov]; Hanley, Mary [Hanley.Mary@epa.gov]; Hughes, Hayley [hughes.hayley@epa.gov]; Hartman, Mark [Hartman.Mark@epa.gov]
Subject: FW: Inside EPA: EPA May Have To Delay SACC's Perc Review Due To Lack Of Advisors

Let me know if this impacts announcing the draft RE and peer review meeting today.

From: Jones, Enesta <Jones.Enesta@epa.gov>
Sent: Monday, April 27, 2020 7:45 AM
To: AO OPA Individual News Clips <AO_OPA_Ind_News_Clips@epa.gov>
Subject: Inside EPA: EPA May Have To Delay SACC's Perc Review Due To Lack Of Advisors

Inside EPA
EPA May Have To Delay SACC's Perc Review Due To Lack Of Advisors
https://insideepa.com/daily-news/epa-may-have-delay-sacc%E2%80%99s-perc-review-due-lack-advisors

EPA may have to postpone its advisors' planned May meeting to review its upcoming percloroethylene (perc) evaluation, the last of the ten toxics law assessments EPA must complete by the end of June, after being forced to postpone their April meeting on its draft asbestos analysis because advisors were unavailable due to the pandemic.

"I've already informed EPA that the May meeting they're trying to hold for perc may have the same problem" as the asbestos peer review meeting, says Ken Portier, chairman of EPA's Science Advisory Committee on Chemicals (SACC), who will be departing the panel later this summer.

His comments, in an April 23 interview with *Inside EPA*, came after EPA announced April 20 that it was postponing the SACC's previously scheduled April 27-30 meeting to peer review the agency's draft evaluation of asbestos because some of the advisors are no longer available, -- a change in course just weeks after officials denied requests from environmentalists and some advisors to delay the meeting because of the pandemic.

The delay all but ensures the agency will not be able to meet its statutory deadline to complete all of the first 10 evaluations that the revised Toxic Substances Control Act (TSCA) requires by an extended June. The agency's toxics chief has already acknowledged that some of the evaluations may "slide" from the June deadline.

Now Portier, a biostatistician retired from the American Cancer Society, says that the SACC meeting EPA was planning to hold in May to peer review the agency's not-yet released draft evaluation of the

common solvent perc might also need to be postponed, especially if coronavirus inspections rates spike.

"If the states open up or release their stay at home mandates too early, [at] the end of May we may be seeing the next peak in coronavirus. I'm worried the same people [who serve on the SACC and are unavailable for the asbestos meeting] will be busy" dealing with public health issues in their states in May.

Asked about the status of the planned May meeting, an EPA spokeswoman says only that the agency's April 20 statement announcing the delay of the asbestos meeting "speaks for itself."

EPA's statement did not address the May meeting. "Given the importance of the draft risk evaluation for asbestos, the Agency believes that rescheduling for a time when more members are available is critical and will allow for a more robust review of the evaluation," it states. "As a result, the SACC meeting will be rescheduled as soon as practicable."

Portier explained that panelists discussed their availability for the April meeting meant and were concerned that they may not be able to muster a quorum for the panel to meet. "Because of the coronavirus too many of them were tied up to continue with the meeting. We told EPA that and recommended they postpone the meeting," he said.

Each SACC peer review meeting includes chartered members of the SACC, as well as ad hoc panelists with expertise in the particular chemical under assessment or associated issues.

Portier explained that to hold its meetings, "SACC is required to have a majority of its charted members at every meeting. Without being able to get a quorum, we couldn't hold a meeting. . . . It's how EPA charters its advisory committees. They all have that stipulation."

Portier clarified that while he did not ascertain exact numbers of advisors who would be unavailable to attend the planned April meeting on asbestos, there was concern that SACC would be unable to muster a quorum. "The people on this committee are exactly the sort of people working on the coronavirus," Portier explained, noting that members include medical doctors, epidemiologists, toxicologists, public health experts and occupational hygienists -- all roles tied into pandemic response.

'Not Unexpected'

"It's not unexpected," Portier said. We were "almost not able to host the [trichloroethylene (TCE) peer review meeting last March] because we could see this was happening."

At the end of the TCE peer review meeting, SACC member Henry Anderson raised concern about the timing of the scheduled asbestos peer review meeting, questioning why it was necessary given the ongoing emergency. Anderson, who retired as Wisconsin's chief medical officer, is assisting state

officials and said he spent the TCE meeting running between his personal computer to monitor the TCE peer review webinar and attending pandemic response planning meetings with state officials in a secured location.

Portier recognizes that EPA officials "want to continue with this TSCA work," noting that Congress' 2016 TSCA reform law "mandated they complete these first 10 chemical [evaluations] by the end of 2019; they're already over the deadline and still have two more chemicals to do."

The reformed statute directed EPA to assess existing chemicals, those that were already in commerce when the original statute took effect in 1976 and largely grandfathered from the original statute, starting with a first batch of 10. The statute provided a December 2019 deadline to finalize these assessments, while also allowing a 6-month extended deadline. EPA is now racing to meet that June deadline for its first 10 assessments, though it has not finalized any of them.

EPA has yet to release its draft evaluation of perc for public comment and peer review, and it is now unclear when SACC might peer review the asbestos or perc drafts.

Portier says that some of the delay in completing the first 10 evaluations came from the delay caused by the federal shutdown in December 2018, which he said "put the committee six months behind. We didn't get started until June [2019]; it's not possible to get through 10 [draft evaluations] at the level we've been looking at these first 10 risk assessments."

Portier added that both committee members and agency staff have been on a "learning curve" to understand what TSCA requires, what EPA is doing and why, and for agency staff to understand "the level of report that the committee is coming to expect. This first 10 [evaluations have been] part of a growth process on both sides. It has really meant a lot of work for the chartered committee. It has been a struggle to get these" reviews done.

Few of the committee members are retired, meaning most are juggling committee work on top of their jobs and other commitments. EPA's pace in recent months has been impressive, releasing a draft evaluation once a month since December. EPA has given SACC about 30 days to review most of the evaluations it before hosting the peer review meeting, despite SACC members' protests.

Once the peer review meeting is complete, the panel has 60 days to finalize its report to the agency, meaning that in recent months, SACC members have been reviewing two draft evaluations simultaneously.

EPA, however, has yet to finalize any of the evaluations -- a point Anderson raised in his remarks at the TCE meeting. He suggested EPA complete some of the evaluations instead of preparing for peer review of the draft asbestos evaluation in April.

SACC's Role

Without completed evaluations, it is unclear how -- or whether -- EPA will respond to the concerns the SACC has raised in its reports on the agency's draft evaluations.

During a recent SACC meeting, EPA's toxics chief Alex Dunn sought to assure the panel that the agency "is listening" to its concerns, citing recent decisions to mandate additional testing of PV29 -- the first draft evaluation it reviewed, though some panelists continued to raise concerns that the agency appears to have ignored many of their other concerns.

Dunn also called for the panelists to encourage colleagues to step up and serve on the panel as the agency prepares to name replacements for a host of departing SACC members.

Portier noted that under SACC's charter, one-third of its members will rotate off the committee in July, including him. "By July, they have to find a new chair," Portier said.

The next panelists will be critical as Dunn has said at several public meetings that EPA intends to shift SACC's role after the first 10 draft evaluations are peer reviewed, and last February, sought SACC's input.

How the panel is overhauled will be significant, as the agency is beginning to evaluate 20 more existing chemicals.

EPA in recent weeks has released its draft scoping documents for its next 20 chemicals, which it is due to finalize in June. Dunn acknowledged at SACC's February meeting to review the draft evaluation of carbon tetrachloride that it would not be possible for SACC to peer review 20 chemicals as it has the first 10 and reiterated her plans to rethink how EPA will undertake peer review of its draft evaluations.

Portier said that SACC's transition is his next project, now that the asbestos meeting has been delayed. "We've started having some limited conversations on how the EPA may" want to do that he said, adding that "one of my tasks next week [will be to] put some of those ideas down on paper so we can get moving on that."

Portier said that EPA and SACC are also learning what expertise is needed on the SACC. "The first time you create this committee you take a guess, and it was a very good guess," Portier said. He said that in retrospect, "it would be nice to have more developmental toxicology people. We haven't really come across a chemical yet that's a significant endocrine disruptor; we don't have that expertise yet." He noted, however, that he raised the issue because half-a-dozen phthalates are among the next 20 chemicals up for evaluation.

Other issues that he sees SACC needing to address include the reformed TSCA's requirement that the agency's evaluations address "potentially susceptible subpopulations (PESS)," groups of people thought to be more susceptible to exposure to the chemical under evaluation because of their lifestage, enhanced exposure or health status, among other factors.

"I still think that . . . we've yet to get a good handle on the [PESS], and to me that's one of those issues that I've been thinking we need a special consultation on that." Portier suggested that SACC members "who understand this [should] spend a couple of days discussing how PESS should be handled in TSCA risk assessments."

Portier acknowledged that some SACC members have also called for someone from OSHA to provide the committee with information on personal protective equipment (PPE) and the hierarchy of controls of different kinds that are used to protect workers on the job. EPA's use of the PPE in its analyses has been an area of controversy and frequent SACC comment in its peer review reports.

"We've been butting our heads over it, but I don't think we've got to the end of that," Portier said of the PPE issue. -- *Maria Hegstad* (mhegstad@iwpnews.com)