Message

From: Fernandez, Cristina [Fernandez.Cristina@epa.gov]
Sent: 1/22/2020 12:16:25 PM
To: Chow, Alice [chow.alice@epa.gov]
Subject: Re: Morning Call - please read.

Thanks

Sent from my iPhone

On Jan 22, 2020, at 6:42 AM, Chow, Alice <chow.alice@epa.gov> wrote:

I am fine with this…

Alice H. Chow
Chief, Air Quality Analysis Branch (3AD40)
USEPA, Region 3
Phone: 215-814-2144
Email: chow.alice@epa.gov

From: White, Terri-A <White.Terri-A@epa.gov>
Sent: Tuesday, January 21, 2020 6:51 PM
To: Davis, Alison <Davis.Alison@epa.gov>
Cc: Nitsch, Chad <Nitsch.Chad@epa.gov>; Fernandez, Cristina <Fernandez.Cristina@epa.gov>; Chow, Alice <chow.alice@epa.gov>; Kim, Lena <Kim.Lena@epa.gov>
Subject: RE: Morning Call - please read.
Importance: High

I'm good with these but I'm looping in our Air program folks who should weigh in and know how the agency is responding.

Terri

Terri A. White
Chief, Communications Branch
Office of Public Affairs
EPA Region 3
215-814-5523
white.terri-a@epa.gov

<image001.png>

From: Davis, Alison <Davis.Alison@epa.gov>
Sent: Tuesday, January 21, 2020 5:36 PM
To: White, Terri-A <White.Terri-A@epa.gov>

Cc: Nitsch, Chad <Nitsch.Chad@epa.gov>
Subject: Morning Call - please read.

Hey Terri
I wanted you to be aware of the draft answers we plan to send to the Morning Call. They are in OAR clearance right now (everything EtO gets reviewed), but I wanted you all to get a look so you can let me know if anything gives you heartburn.

We have two pieces to this:

1) Answers to some followup questions the reporter sent. They all focus on rulemaking and the section 114 letters we sent to sterilizers.
2) Some clarification to a paragraph in her January 19 story. We're not asking for a correction, but want to help her get the difference between commercial and hospital sterilizers straight – so she gets things right going forward.

Here's what's being reviewed:

Follow-up questions and answers.

As the U.S. EPA pursues its mission to protect human and environmental health, addressing ethylene oxide is a priority for the Agency. EPA is following a two-pronged approach to address ethylene oxide emissions. In the first prong, we are reviewing regulations for facilities that emit ethylene oxide – starting with the National Emissions Standards for Hazardous Air Pollutants (NESHAP) for miscellaneous organic chemical manufacturing facilities and the NESHAP for commercial sterilizers. In the second prong, EPA is working with states as they gather additional information on facility emissions to determine whether more immediate emission reduction steps are needed. Below are answers to your follow-up questions about the regulations review.

The commercial sterilizers: that's like B. Braun, Sterigenics right? companies that sterilize medical equipment (but **are not located at** health care facilities?)
Answer: That's right, with the addition underlined in bold above. There is a separate rule for hospital sterilizers.

What's the timeline for revised standards?
Answer: EPA anticipates issuing a proposal in mid-2020 for public review and comment.

And you said the EPA sent info request to commercial sterilizers, does that include B. Braun?
Answer: In order to get the most representative information about the industry, EPA's request went to companies that own numerous sterilizers, and that are a mix of small and large businesses and geographic locations. B. Braun was not included in this request.

Lastly, Pennsylvania Department of Environmental Protection said it uses EPA standards for EtO emission caps (which is 10 tons). Is that right?

On background:
Not quite. Pennsylvania does implement EPA's National Emissions Standards for Hazardous Air Pollutants (NESHAP) for ethylene oxide sterilizers. Those standards comprise several requirements – including a requirement that facilities that use 10 tons or more of ethylene

oxide a year control ethylene oxide emissions from sterilization chamber vents and aeration room vents by 99 percent (this includes B. Braun).

Also on background:

There is some incorrect information in this paragraph in your story from January 19. Noted below

"EPA officials said the agency is working on revising regulations for hospitals and factories that use the chemical. In November, the agency proposed changes that would reduce ethylene oxide emissions for chemical manufacturing companies by 93%. The agency held two public hearings on the proposals this month and will take written comment until Feb. 18. The agency is also seeking public comment until Feb. 10 for proposing new standards for companies that use sterilizers, which doesn't include hospitals."

As a reminder, EPA has two regulations for sterilizers

- A regulation for *commercial* sterilizers (these are not located at hospitals, although commercial sterilizers do sterilize medical equipment). This regulation is under review. Braun is a commercial sterilizer.
- A regulation for *hospital* sterilizers (smaller sterilizers located at hospitals). This regulation is not currently being reviewed.
- The public comment we are seeking until February 10 is data and information to inform a proposed rule for commercial sterilizers (the rule we are reviewing). Note that our rule regulates the facilities that do the sterilization -- not the companies that send items to them to be sterilized.