Message (Digitally Signed)

From: Sharon Lerner [sharon.lerner@theintercept.com]
Sent: 12/21/2021 3:09:30 PM
To: Hamilton, Lindsay [Hamilton.Lindsay@epa.gov]
CC: Daguillard, Robert [Daguillard.Robert@epa.gov]; Carroll, Timothy [Carroll.Timothy@epa.gov]; Dunton, Cheryl [Dunton.Cheryl@epa.gov]
Subject: Re: Next whistleblower piece
Attachments: signature.asc

Hi Lindsay-
I just wanted to follow up because, upon reading your response, I fear that I didn't make it clear that I already discuss the memo you attached in the story. In fact I link to it. And I note that the majority of scientists who were discussing the issue of PCBTF in the paint assessment did NOT agree with the interpretation you give of the memo - that it meant that it was subject to the polymer exemption. To be clear, that was the central dispute, the whistleblowers (3 in this case) and several other EPA staff members who were involved in the discussions — and whose emails I've reviewed — did not believe that the memo made it clear that the dangers of PCBTF should not be included in the assessment. Instead, they had a variety of interpretations of the memo, including that 1) the dangers of PCBTF should be included in the assessment, 2) PCBTF should be sent to the existing chemicals for assessment, 3) if NCD did not include the risks in the assessment, other actions should be taken.

One whistleblower said: "There's a final paragraph stating that if there is nothing done, if we're not going to do the review ourselves, at a bare minimum, the risk managers should be communicating what we found to the chemical company so that they know that they have to take some sort of action."

I'm just sending this in case you want to clarify your response at all.
Thanks,
Sharon

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On Dec 20, 2021, at 8:26 PM, Hamilton, Lindsay <Hamilton.Lindsay@epa.gov> wrote:

Hi Sharon,

Here is a response for you. Thanks so much.

EPA and the Office of Chemical Safety and Pollution Prevention are committed to the agency's mission to protect human health and the environment.

Regarding the specific PMN in question:

The PMN substance that is the question of this inquiry is a polymer contained in a paint. The PMN substance is a polymer and it qualifies for the polymer exemption.

As background, the 1985 memo, attached, describes how to address a circumstance in which an existing chemical is included as an intentional component of a PMN substance and when that existing chemical poses risk. Under the referenced policy, the solvent would be referred to the Existing Chemical Program and would not be addressed under the new chemical review because the solvent in question is not intentionally part of the PMN substance. The relevant language from the memo that describes this exemption is found on page 9, item #1. The 1985 memo, while written in the context of TSCA as it existed in 1985, contains guidance that remains useful in reviewing new chemicals under the amended law.

When Congress wrote TSCA in 1976 it exempted every chemical in commerce from having to go through the new chemicals assessment process. The 2016 amendments to TSCA direct EPA to do risk evaluations on the existing chemicals that were grandfathered in under the original law and requires EPA to have at least 20 risk evaluations in process at any given time. EPA is meeting those requirements. While one can accurately state that many of the chemicals that were grandfathered into the 1976 law may pose risks and remain unrestricted under TSCA, the PMN substance subject to this inquiry was not handled inappropriately or inconsistently with TSCA.

Regarding scientific integrity:

Restoring scientific integrity has been a top priority across the Agency since the beginning of the Biden-Harris Administration. Significant efforts are underway to understand and address concerns that have been raised. We are continuing to make improvements to the program and are cooperating fully with the ongoing IG investigation.

EPA's new chemicals program has been engaging in targeted, all-hands-on deck efforts to catalogue, prioritize and improve its procedures, recordkeeping and decision-making practices related to review and management of new chemicals under TSCA. The new chemicals program has already implemented several important changes to provide additional opportunities for resolution of differing scientific opinions, and to allow input into the decision-making by EPA subject matter experts outside of the division. This includes, for example, a revised process for review and finalization of human health risk assessments, and the formation of a new advisory body within the program to review and consider both scientific and science policy issues related to new chemical submissions.

The following are examples of additional actions OCSPP has already taken to address scientific integrity concerns across the office:

- Ongoing cooperation with Inspector General's investigation;
- Implementation of several new processes for scientists to elevate their concerns and get a review wherever there's disagreement;
- A change in the performance metric for the New Chemicals Division, such that expediency of reviews is not the only measure of success, see FY 2022-2026strategic plan draft;
- Series of scientific integrity trainings for the entire office to emphasize the importance of these policies;
- Independent contractor review of the TSCA New Chemicals program to capture feedback from employees and management about any potential workplace barriers and opportunities for organizational improvement; and
- Ongoing collaboration with EPA's Office of Research and Development on furthering scientific research relevant to new chemical reviews.

Responses to your specific questions:

QUESTION: IS THIS ACCURATE, THAT MANUFACTURERS "ALMOST ALWAYS" SUBMIT THE INFORMATION ABOUT THEIR PRODUCTS IN PMNS AS CBI? OR IS IT ALWAYS THE CASE? OR JUST SOMETIMES?]

EPA often receives CBI claims associated with various information within PMNs, and the specific claims (i.e., types of information claimed as CBI) will vary case to case.

[QUESTION: WHEN ARE THOSE 20 ASSESSMENTS EXPECTED TO BE FINALIZED?]

The policy changes associated with TSCA risk evaluations that were announced on June 30 will be carried through to all future risk evaluations, including the next 20 and ongoing manufacturer requested risk evaluations. The Agency is reviewing the next 20 chemicals to determine the extent of the effect of policy changes on the scopes of the risk evaluations. Upon completion of this review, EPA intends to provide updates regarding any changes. Generally, these risk evaluations represent a multi-year effort that, under TSCA, can take up to 3.5 years from the designation as a high-priority chemical to complete.

[QUESTION: IS THERE ANY UPDATE ON THIS? ARE THE 8ES AVAILABLE YET IN CHEMVIEW?]

Due to overarching (staff and contractor) resource limitations, the agency was not able to continue the regular publication of 8(e) submissions in ChemView, a heavily manual process, after 1/1/2019. EPA has continued to take in and review 8e submissions; however, a single staff person was dedicated to processing the submissions for posting to ChemView. That staff person retired in December 2018. Other staff within the unit that would historically also do this type of work were fully occupied conducting other work to increase transparency associated with TSCA new chemicals submissions in response to a commitment made by the past EPA Administrator to Senator Carper. See:https://insideepa.com/daily-news/win-dunns-confirmation-epa-vows-revise-key-tsca-programs.

The TSCA program has been and remains incredibly underfunded. The previous Administration never asked Congress for the necessary resources to reflect the agency's new responsibilities under amended TSCA. The Biden-Harris Administration has asked for significantly more resources for this program in the 2022 budget request to ensure we're meeting our obligations under TSCA, most importantly protecting human health and the environment.

In the future, as resources allow, EPA will continue to strive to make TSCA 8(e) reports publicly available in ChemView in the interest of increased transparency. In the meantime, in 2021 EPA reinstated contractor funding to ensure all TSCA 8(e) reports receive initial screening and any serious health and safety risks are flagged for further review. EPA is also currently transforming the 8(e) publication process to be more automated and to the extent that resources allow, will resume making these submission types publicly available in ChemView again soon.

Thanks,
Lindsay

From: Sharon Lerner <sharon.lerner@theintercept.com>
Sent: Monday, December 20, 2021 11:37 AM
To: Daguillard, Robert <Daguillard.Robert@epa.gov>
Cc: Carroll, Timothy <Carroll.Timothy@epa.gov>; Hamilton, Lindsay <Hamilton.Lindsay@epa.gov>; Dunton, Cheryl <Dunton.Cheryl@epa.gov>
Subject: Re: Next whistleblower piece

Yes confirming that we can update at any point after publication.

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On Dec 20, 2021, at 11:35 AM, Sharon Lerner <sharon.lerner@theintercept.com> wrote:

We can update at any point, I believe. I put in a note to my editor to confirm, will let you know as soon as he gets back to me.

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On Dec 20, 2021, at 11:27 AM, Daguillard, Robert <Daguillard.Robert@epa.gov> wrote:

Thanks, Sharon. Duly noted. How late can you update your story?

From: Sharon Lerner <sharon.lerner@theintercept.com>
Sent: Monday, December 20, 2021 11:24 AM
To: Daguillard, Robert <Daguillard.Robert@epa.gov>
Cc: Carroll, Timothy <Carroll.Timothy@epa.gov>; Hamilton, Lindsay <Hamilton.Lindsay@epa.gov>
Subject: Re: Next whistleblower piece

Robert-
This is going to come out tomorrow. So sorry for the shorter than usual turnaround time

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On Dec 20, 2021, at 9:08 AM, Daguillard, Robert <Daguillard.Robert@epa.gov> wrote:

Sorry, Sharon: I'm sure you realize this week will see lighter-than-usual staffing: We're closed Friday, to say nothing of staff going on leave beforehand. Are you planning to put this piece out any time before, say, the first of the year? How urgently do you need it?

Thanks as always, R.

From: Daguillard, Robert <Daguillard.Robert@epa.gov>
Sent: Monday, December 20, 2021 9:04 AM
To: Sharon Lerner <sharon.lerner@theintercept.com>
Cc: Carroll, Timothy <Carroll.Timothy@epa.gov>; Hamilton, Lindsay <Hamilton.Lindsay@epa.gov>; EPA Press Office <Press@epa.gov>
Subject: RE: Next whistleblower piece

Good morning Sharon,

I know your message is addressed to Tim and Lindsay, but I wanted to acknowledge on their behalf.

Best as always, R.

From: Sharon Lerner <sharon.lerner@theintercept.com>
Sent: Monday, December 20, 2021 8:53 AM
To: EPA Press Office <Press@epa.gov>
Cc: Carroll, Timothy <Carroll.Timothy@epa.gov>; Hamilton, Lindsay <Hamilton.Lindsay@epa.gov>
Subject: Re: Next whistleblower piece

Hi Tim and Lindsay-
Just circling back on this to make sure you received it.
Thanks,
Sharon

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On Dec 17, 2021, at 10:19 AM, Sharon Lerner <sharon.lerner@theintercept.com> wrote:

Hi Tim and the press office-

I am writing with questions regarding the next article in the series based on the EPA whistleblowers. I am basing the piece, which I've summarized below, on interviews with several EPA employees as well as documents they have shared with me, including screenshots of emails. I am asking whether you want to comment on any of what I've written below and have highlighted in yellow three questions.
Can you please get me your response by the end of the day on Monday?
Thank you,
Sharon

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In this piece, I write about the assessment of a paint product that was finalized on December 19, 2019. The paint contained the solvent parachlorobenzotrifluoride, or PCBTF, which made up half of the product by weight. PCBTF presents numerous health hazards, according to a 2009 report from the National Toxicology Program. Earlier in 2019, California had listed PCBTF under Proposition 65, basing its decision on evidence that the chemical had caused liver tumors in both male and female mice. And just month before the product was being assessed by EPA's NCD, the International Agency for Cancer Research had deemed PCBTF a likely human carcinogen.

The toxicologist who was assigned the case of the paint noted that it contained PCBTF and engaged in conversations - in person and over email - about how to handle it. While numerous assessors agreed that the risks of PCBTF should be included in the assessment of the new paint, one official, who holds a senior

leadership role in the agency, said she felt that the dangers of PCBTF should not be mentioned in the assessment. In a December 18 email, she described the chemical as "just a solvent there as a part of making it." She argued that, because it didn't appear that PCBTF was meant to be an ingredient in the final product, its health effects should not be considered in the assessment.

The official, whom the whistleblowers asked me not to name in the piece, also pointed the assessors to a 1985 memo, which addressed when EPA should assess the risk from a new chemical substance. The whistleblowers describe her as angrily throwing the memo at them and said that tensions with this official over identifying chemicals' risks were running high.

The official saw the memo as evidence that PCBTF shouldn't be considered when assessing the paint and told the toxicologists assembled at the meeting to "Read it. Follow it." But several of the assessors interpreted the memo differently, pointing out that some sections seemed to support the inclusion of PCBTF in the assessment and noting that others laid out the possibility of referring the compound to the Existing Chemicals program for assessment. The memo also laid out other actions to be taken if the new chemicals division did not assess the product.

"There's a final paragraph stating that if there is nothing done, if we're not going to do the review ourselves, at a bare minimum, the risk managers should be communicating what we found to the chemical company so that they know that they have to take some sort of action," one of five agency scientists whoexpressed their support for including the dangers of PCBTF in the assessment of the new paint said. This did not happen, according to the whistleblowers.

"It does seem that we need to be concerned about the risk of the new

chemical plus existing chemicals that pose risk," another of the toxicologists wrote. "I think the human health assessors need to feel comfortable that we are doing our best to protect public health." Another concurred, noting that "several of us spoke to NCMB [New Chemicals Management Branch] in mid-October about this and they supported assessing residuals, impurities" for risk assessments.

But the hazards presented by PCBTF were not included in the assessment of the paint. In a version of the document entered into the division's computer system on December 17, the toxicologist had noted that PCBTF can be absorbed through the lungs, GI tract, and skin. He also identified cancer as one of its hazards, along with liver, kidney, lung, and adrenal gland effects, and calculated the cancer risk associated with precise amounts of the paint. But the next day, hours after the contentious meeting at which the memo was discussed, the official who had argued against the inclusion of the information inserted a note into the assessment, asking him to delete all references to PCBTF.

The toxicologist did not delete the information, but the official who had led the charge against making any mention of the risks of PCBTF did. On December 18, she posted an updated version of the assessment that crossed out the list of PCBT's effects and the exposure levels above which it could be expected to cause cancer. In its place, she inserted a new sentence: "For the new chemical substance (polymer), EPA did not identify a hazard." The next day, she signed off on the document she had changed, publicly declaring that the agency had found that it did not pose a hazard.

The whistleblowers said that the removal of the scientifically accurate warning left the scientists who do chemical assessments feeling powerless to do their jobs — and win an argument within their workplace

on its merits. "You've got multiple people saying, hey, this deserves more careful consideration. But she made a call, overrode everybody, shut it down, and we never talked about it again," said one.

The whistleblower said that EPA could have taken several possible actions to alert the public about the paint. "But the conversation is not 'what can we do within these limitations?'" he said. "Instead their question is, 'how little can we get away with? What can we get off our plate?'"

He also said that "When new information comes in that shows that something is less toxic than what we thought, that gets used right away. But if it shows that there are new concerns that we weren't aware of before, suddenly the level of scrutiny goes way up."

I asked David Michaels, the former head of OSHA, about this case, which involves the potential exposure to workers. And he said "The EPA is supposed to be considering whether workers' exposures could be toxic. This is a failure of EPA to follow the law."

I note in the story that the whistleblowers are not allowed to disclose the products name or anything else about it because, as is almost always the case, the manufacturers submitted those details to the agency as confidential business information. [QUESTION: IS THIS ACCURATE, THAT MANUFACTURERS "ALMOST ALWAYS" SUBMIT THE INFORMATION ABOUT THEIR PRODUCTS IN PMNS AS CBI? OR IS IT ALWAYS THE CASE? OR JUST SOMETIMES?]

I note that the staffers could face penalties if they disclosed them and that they can identify PCBTF without penalty because, as an existing chemical, it is not subject to the same restrictions.

I note that the paint is not the only product that contains PCBTF and that none of 7 safety data sheets I found for products that contain it identified the risk of cancer. I also

note that there are many chemicals for which the EPA has failed to update regulation based on the most recent science.

"We never go back and review these cases and put on new restrictions for their use," said one of the whistleblowers.

I note that the EPA chose 20 "high priority" substances to be evaluated under the updated chemicals law in 2019. [QUESTION: WHEN ARE THOSE 20 ASSESSMENTS EXPECTED TO BE FINALIZED?]

I also note that there is no clear way to ensure that the agency updates its assessments — or even informs anyone — when it learns about the harms of a chemical and refer back to my recent story on 8e submissions. [QUESTION: IS THERE ANY UPDATE ON THIS? ARE THE 8ES AVAILABLE YET IN CHEMVIEW?]

Finally, I note that the whistleblowers found experience of being unable to persuade their superior of the importance of warning the public about PCBTF both frustrating and baffling.

"Why would someone hear that there's a cancer risk for workers and not even let people know about it?" One asked. "Why would they think that that's something that can just be ignored?"

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<Risks of existing chemicals in PMNs (002).pdf>