

## EPA's Failure to Consider New Toxicity Information

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**Summary.** EPA is failing to update completed risk assessments with new information coming into the Agency, and this is resulting in risks to the public. PEER's latest disclosure, submitted to the Inspector General (IG) on behalf of two of our EPA clients, provides a specific example where new information on an existing chemical, parachlorobenzotrifluoride (PCBTF), shows that this chemical is a probable animal carcinogen. However, when staff in the New Chemicals Division (NCD) raised the issue, they were prevented from evaluating potential risks to workers or the public due to its status as an existing chemical.

New risk information on existing chemicals is not considered: the case of PCBTF. EPA's failure to re-assess existing chemicals based on new data in the open literature ignores risks to workers and the general population. This issue is exemplified by a case from 2019, where a new chemical included parachlorobenzotrifluoride (CAS # 98-56-6; aka PCBTF) as a solvent, which is an existing chemical. The failure to re-examine the toxicity of PCBTF in light of the latest toxicity data published four years earlier presents an imminent danger to human health. CalEPA added PCBTF to their Prop 65 list of chemicals "known to the state of California to cause cancer" on June 28, 2019 based on these data.

*PCBTF is Listed by EPA as a VOC Exempt Chemical.* EPA by policy encourages the use of PCBTF along with other "VOC [volatile organic compound] exempt" chemicals<sup>1</sup>. VOCs react with nitrogen oxides on hot days to create ozone, and are defined by EPA as "any compound of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions."<sup>2</sup> Because some VOCs are slow to react (this does not mean that these chemicals are not volatile), EPA has determined that these VOCs have "limited effects on local or regional ozone pollution episodes."<sup>3</sup> Therefore, EPA carved out VOC exemptions for pure chemicals that are slow to react. PCBTF is considered a VOC exempt chemical. VOC exemptions are geared toward reducing ozone levels, and do *not* take into account the toxicity of the chemical itself to human health. Because PCBTF is a VOC exempt chemical, it is promoted by companies as a "green" alternative.

*PCBTF is a High Production Volume Chemical.* PCBTF is used as an intermediate in the synthesis of dyes, pharmaceuticals, pesticides, insecticides, and herbicides, and as a

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<sup>1</sup> Accessed 10-15-2021 from: <https://www.epa.gov/ground-level-ozone-pollution/complete-list-voc-exemption-rules>

<sup>2</sup> 40 CFR 51.100(s)

<sup>3</sup> <https://www.epa.gov/ground-level-ozone-pollution/volatile-organic-compound-exemptions>

solvent, mainly in paint and coating formulations.<sup>4</sup> Further, PCBTF has applications in household and industrial cleaners and degreasers as well as in inks and digital inks, where it is used to dissolve ink.<sup>5</sup> The Chemical Data Reporting (CDR) data for PCBTF indicate that it is a High Production Volume (HPV) chemical. In 2011, the national aggregate volume was 28,964,014 pounds and, between 2012 and 2015, the range was reported to be between 10,000,000 and 50,000,000 pounds.

*New Data Indicate that PCBTF is an Animal Carcinogen.* In 2018, the National Toxicology Program (NTP) published a cancer bioassay in rats and mice that concluded that there was clear evidence of carcinogenic activity in male mice based on an increased incidence of liver tumors, and in female mice based on an increased incidence of liver and Harderian gland<sup>6</sup> tumors. Based on these findings, PCBTF was listed as “known to the state of California to cause cancer” as of June 28, 2019. Despite the new hazard data and significant exposures, EPA staff were not allowed to assess PCBTF risks.

*The 1985 memo.* A 1985 memorandum entitled “PMN Policy Guidelines Memorandum #2: Review of Risks Posed by Existing Chemicals in the New Chemicals Program” (hereinafter “1985 Memo”) is to be consulted when deciding the circumstances under which it is appropriate to calculate/assess risk for an *existing* chemical. However, management argued that because the existing chemical was not intended to be part of the structure of the new chemical substance, that they should not assess it. However, the memo explicitly states that “[t]he NCP should refer to the ECP [Existing Chemicals Program] a potential unreasonable risk posed by activities involving a PMN substance where the PMN substance by itself does not support the risk finding where the risk represents but a single manifestation of an existing, widespread, and generalized problem.”

On December 19, 2019, the determination document for this new chemical was signed by EPA management and concluded that the chemical substance was not likely to present risks.

**What should EPA have done?** Many new chemicals are manufactured, processed, distributed, used, and disposed of in ways where exposure to chemicals already on the Inventory may lead to unreasonable risks to workers, consumers, and/or the general population, including unreasonable cancer risks. These risks may not have been known or understood at the time the existing chemical was first reviewed, either because it was grandfathered in under the first Toxic Substances Control Act in 1976 or because the data were developed after the chemical was brought to market, or both. To support their limiting interpretation of the Agency’s

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<sup>4</sup> [https://www.ashland.com/file\\_source/Ashland/Documents/Sustainability/rc\\_parachlorobenzotrifluoride\\_pss.pdf](https://www.ashland.com/file_source/Ashland/Documents/Sustainability/rc_parachlorobenzotrifluoride_pss.pdf)

<sup>5</sup> <https://www.wegochem.com/news/24/Wego-is-a-global-supplier-of-Parachlorobenzotrifluoride>

<sup>6</sup> A secretory gland that lubricates the eyes and eyelids.

authorities, some EPA managers have referred to a 1985 memorandum that sets forth guidelines for managing risks for new versus existing chemicals.

PEER believes that: 1) the memo does *not* preclude EPA from managing risks from existing chemicals under Section 5 of TSCA, and in fact explicitly contemplates these scenarios, indicating particular courses of action depending on the circumstances; 2) even if the memo were to preclude EPA from managing risks from existing chemicals under Section 5, the 2016 Lautenberg Act amended TSCA in such a way that would allow it to do so now; and 3) even if both the memo and the Lautenberg Act were to preclude EPA from managing risks from existing chemicals under Section 5, the Agency still has a duty to notify the manufacture/processor/distributor and the general public of the unreasonable risks it found so that these parties are equipped with the knowledge they need to take voluntary actions to mitigate risk.

The 1985 memo dictates how EPA should handle situations where a new chemical poses a potential unreasonable risk when the new substance itself is not the reason for that potential risk. While the memo states up front that “[t]he crux of the policy is to limit NCP actions on potential unreasonable risks, which, by their nature or magnitude, are essentially new risks,” it is clear that the memo also considers situations where, for example, new information has become available on an existing chemical, and this existing chemical is a solvent that is intentionally added and remains with the new substance being assessed. Indeed, the last paragraph of the 1985 memo states:

Whenever the NCP identifies a concern for an unreasonable potential risk from an associated existing chemical and does not address the potential risk in the NCP because it would be more appropriate to refer the case to the ECP, the Chemical Control Division will inform the submitter of the potential risk in writing, and, if appropriate, recommend voluntary use of protective equipment (emphasis added). This will, at minimum, put the submitter on notice that failure to address the risk could be hazardous to its employees and/or customers, and could subject the submitter to future product or negligence liability.”<sup>7</sup>

In this case, the solvent PCBTF presents an unreasonable risk as a substantial part of the new chemical substance, and as such, NCD should have referred the issue to Existing Chemicals for review. Failure to do so puts workers, consumers, and the general population at risk.

In conclusion, both TSCA and the 1985 memo give EPA the authority to address the risks posed by PCBTF in the new chemical substance. The 1985 memo prevails as currently applicable guidance.

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<sup>7</sup> Id. at 10



The 1985 memo gives NCD and/or Existing Chemicals the authority to address the risk associated with the entire substance, depending on the particular facts at hand. The public expects the EPA to protect them from toxic substances. Especially given that new chemicals have no data requirements, one would think that as data are developed after a chemical goes on the market that it would have some sort of impact. Most people would assume when EPA becomes aware of toxicity data on a chemical that it takes action to address risks to workers and the public. The public expects us to control toxic substances.