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The Continued Challenge Presented by Exposure Considerations in EPA Risk Evaluations

November 18, 2020

This article was originally published in Wiley's The WELL blog.

This week, Erik and I were communicating with a friend and colleague who is an expert technical consultant for TSCA risk evaluations. Specifically, we were exchanging emails on how EPA interprets conditions of use. Our "virtual" conversation prompted me to look this morning at the PV 29 updated risk evaluation – comments are due on EPA's update to this document by December 19, 2020.

Based on particle size data that were submitted in response to the agency's data call in, EPA is now estimating exposure to this pigment based on a particle size of 0.043 µm, using carbon black (and its known lung overload effects) as a surrogate, and assuming the use of APF 10 respirators in the workplace. This is a trifecta of conservative assumptions that are obviously the basis for why the agency has changed its mind on PV 29: once thought to pose no unreasonable risks, the updated risk evaluation proposes to classify PV 29 as presenting an unreasonable risk in the workplace from its manufacture and import all the way downstream to virtually every use including as an intermediate to adjust color, incorporation into paints and coatings used primarily in the automobile industry, incorporation into plastic and rubber products used primarily in automobiles and industrial carpeting, use in merchant ink for commercial printing, and use in consumer watercolors and artistic color.

Beyond these "application" conditions of use, note the emphasis on particle size, production volume (projected quantities needed to achieve "overload"), and personal protective equipment (PPE). These

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factors are also within the concept of "conditions of use," whereby EPA is considering all manners in which the chemicals under evaluation are handled in workplace settings. EPA is closely evaluating factors like the physical form of the chemical during use and the engineering controls that are part of the process to prevent exposure. So, for example, the PV 29 draft risk evaluation is proposing to employ the absolute smallest measured particle in the data submitted to the agency but it does not transparently communicate what the actual percentage of respirable size particles are of that specific size. This demonstrates the importance of considering how to present particle size data to EPA. Given that PV 29 is only produced at about 500,000 – 600,000 pounds per year, as consistently shown by CDR data, it is not clear how lung overload quantities could be achieved in that particle size range and thus why an unreasonable risk finding actually – as opposed to conceptually – exists.

According to the Center for Chemical Safety Assessment, "the concept of 'lung overload` was first introduced by Morrow in 1988 who defined it as an impairment of alveolar macrophage-mediated lung clearance following exposure to high concentrations of low soluble particles of low inherent toxicity (PSP), thereby triggering accumulation of particles in the deep lung, persistent pulmonary inflammation, epithelial cell proliferation as well as non-neoplastic and in the case of rats also to neoplastic lung lesions." It's been a popular scientific concept used predominantly in Europe for making precautionary findings of risk for chemicals with otherwise low inherent toxicity. Simply put, when the rats that have been studied inhale enough particles in their lungs, their bodies can't clear all of it and they develop a lung tumor formation response around the particles and/or morbidity – they die. As the Center's piece points out, however, "lung tumors following chronic exposure to PSP have been reported exclusively in rats, but not in mice, hamsters, non-human primates or humans." Moreover, "epidemiological studies to date have not found comparable `lung overload` conditions in workers exposed chronically to PSPs, not even in former coal miners having experienced worst-case exposure conditions. Furthermore, well-conducted epidemiological studies thus far have not been able to detect an association between occupational exposure to PSPs and an increased risk for cancer."

TSCA always has been heavy on the science, and this will only become more pronounced as these risk evaluations continue to emerge. It's why technical experts in risk assessment are so important to have on hand if your chemical or use is subject to a section 6 risk evaluation. Industrial hygiene expertise, in particular, is necessary in and outside of the agency, to more fundamentally understand the science behind workplace exposures. It is also why a risk management procedural framework rule is needed so we have fair and objective guardrails for protecting public health and the environment at a critical point in the section 6 process – the end.

Have you had the chance to review the recommendations issued on November 10 by the Program on Reproductive Health and the Environment (PRHE) at UCSF? The recommendations on chemical policy, systematic review, conflicts of interest, environmental justice, data infrastructure, and research funding are essentially a challenge to all of us to dig in harder on bringing sound science to the table for these risk assessments.

The conservative assumptions in the PV 29 risk evaluation are not unique – we are seeing them (and will continue to see them unless fundamental changes are made) across the board. If their use persists, they will become the standard. Historically, TSCA is systematic in the following sense – by doing chemical evaluations in the same procedural way with a consistent methodology, like parties are treated similarly and the appearance of unfair (or favorable) treatment of some over others is avoided. It's the classic box of "This is the way." This TSCA mindset is unlikely to change, nor should it, providing that the tools in the tool box are current and honed.

With respect to conditions of use, when TSCA was updated in 2016, one of the concepts behind including this term in the safety standard for section 6 was to direct EPA to look at the conditions of use that the existing chemical was being manufactured for at the time of the risk evaluation. The concept was applications focused, with no implications assumed. The idea was that these were mature chemicals, with known markets, with minimal innovation around them or that could be "reasonably foreseen." Some of us may have assumed that because these chemicals had been used for many years there was a low likelihood that companies were handling them improperly or that they would innovate with mature chemistry. It was another version of "This is the way." However, because these chemicals are on the Inventory, anyone can make them. As a result, EPA has to review both the applications and implications of chemicals, even in ways that they are not used right now, if those circumstances are in fact reasonably foreseen. There should be a logical outgrowth rationale associated with a reasonably foreseen determination so it is grounded. Is it reasonable for EPA to assume the quantities of PV 29 may quadruple in the future? Based on CDR data, probably not.

TSCA is forcing EPA to become competently expert on these chemicals. Under Chevron, EPA's determinations and assumptions in science-based areas will be given deference. Where stakeholders disagree, their concerns need to be bolstered by sound science and by marshalling well-supported, factual arguments that a condition of use is not likely. Building a factual record of support during the risk evaluation process is essential for challenging unreasonable risk determinations down the road.

With rare exception, no one likes to be referred to as "unreasonable" – or told they are the source of a risk that is "unreasonable." We need to be careful and reasoned in coming to these conclusions, which by definition represents that the activity is beyond the limits of safety, acceptability or fairness. Well-established conditions of use, sound science, good data, and more effective models are needed for making reasonable findings of unreasonable risk. Four years post-Lautenberg, we are still in the early stages in the development of this program. Information and the right expertise remain a real need on the exposure side of the equation in these risk assessments.