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US Ninth Circuit On Glyphosate Prop 65 Listing Could Have Big Implications For TiO₂ And Beyond

by [Ryan Nelson](#)

Industry complaints about California's Prop 65 program are nothing new, but First Amendment cases against the state's attorney general currently moving through California federal courts could have novel, outsized impacts. The Personal Care Products Council, which is suing over a titanium dioxide listing, awaits a review of glyphosate litigation pending in the Ninth Circuit.

A coming US Ninth Circuit decision could clear a path for the Personal Care Products Council's suit against California in a Prop 65 dispute over titanium dioxide.

PCPC is suing in California's Eastern District to enjoin the California attorney general and private enforcers from taking action against companies that fail to warn consumers about potential titanium dioxide (TiO₂) exposures when using beauty and personal-care products, arguing that no California agency or "any other regulatory agency anywhere in the world" has determined that TiO₂ in any form causes cancer in humans.

Meanwhile, the Ninth Circuit is considering a case brought by the National Association of Wheat Growers and like-interested organizations, which moved the same California federal court in June 2020 to permanently enjoin the California AG and all persons or entities in privity with him from requiring or enforcing a Prop 65 warning for glyphosate.

Glyphosate is a widely used broad-spectrum herbicide known by the trade name Roundup, which Monsanto brought to market for agricultural use in the 1970s.

NAGW argues that the required warning for glyphosate – which was listed under Prop 65 as a

substance known to the state to cause cancer in July 2017 – is a First Amendment violation. It notes glyphosate’s approval by the federal government for use in more than 250 agricultural crop applications in all US states. According to the plaintiff, glyphosate is regarded as one of the safest herbicides ever developed.

“[The US Environmental Protection Agency] has repeatedly concluded under FIFRA that use of glyphosate in accordance with federal label instructions does not present any unreasonable adverse effects on human health or the environment, and specifically that glyphosate is not a carcinogen,” NAGW notes in its [complaint](#) filed in November 2017.

“Likewise, California itself has twice examined glyphosate in its own reviews – in 1997 and in 2007 – and on both occasions concluded that glyphosate is ‘unlikely to pose a cancer hazard to humans.’ ... The same is true for every other regulatory body worldwide that has evaluated glyphosate,” the plaintiff says.

NAGW underscores the particular route by which glyphosate came to be Prop 65-listed.

“Under what California refers to as its ‘Labor Code’ listing mechanism under Proposition 65, certain determinations by a foreign non-governmental entity known as the International Agency for Research on Cancer (IARC) automatically require a Proposition 65 cancer listing no matter whether the IARC determination is supported by the consensus of worldwide scientific bodies or not.” (Also see "[Clarified Prop 65 Aloe Vera Listing Largely Resolves Cosmetic Concerns](#)" - HBW Insight, 9 Dec, 2015.)

NAWG continues, “Indeed, a listing under the Labor Code mechanism is automatically required even if IARC is absolutely alone in its views, as is the case here where IARC’s conclusion is opposed by every global regulatory body that has examined the issue, including OEHHA [California’s Office of Environmental Health Hazard Assessment] itself.”

By compelling it and other entities to make false, misleading, and highly controversial statements about their products, California’s listing of glyphosate as a carcinogen and the attendant warning requirement violate the First Amendment of the US Constitution, the plaintiff says.

California’s Eastern District agreed. Its decision relied on a four-decade-old US Supreme Court case, *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*. There, the Supreme Court held that

a state can require commercial speech to include (italics added) “purely *factual* and *uncontroversial* information” without violating the First Amendment provided that the state’s

Consider The ‘Ordinary Consumer’

disclosure requirements are reasonably related to a state interest in preventing deception of consumers.

The California federal court acknowledged the state's interests in the glyphosate matter, but was not persuaded that the Prop 65 compelled speech satisfied the factual and uncontroversial criteria.

Among its [summary judgment findings for NAGW](#), the court wrote, “[I]t is inherently misleading for a warning to state that a chemical is known to the state of California to cause cancer based on the finding of one organization . . . when apparently all other regulatory and governmental bodies have found the opposite.”

The court notes its decision does not bear on certain questions including “whether Proposition 65’s statutory and regulatory regime was good policy,” though the decision no doubt will resonate with Prop 65 critics and, if affirmed by the Ninth Circuit, could spawn more First Amendment suits.

TiO2 Not Carcinogenic To Humans

PCPC takes a similar tack in its 26 May [complaint](#) against the California AG over TiO2’s listing and enforcement prospects.

The suit comes as hundreds of cosmetic and personal-care product manufacturers are being sued in California state courts by Environmental Health Advocates, Inc. for alleged Prop 65 warning noncompliance.

US district judge William Shubb on Prop 65’s required glyphosate warning:

‘While it may be literally true that California technically ‘knows’ that glyphosate causes cancer as the State has defined that term in the statute and regulations, the required warning would nonetheless be misleading to the ordinary consumer. ...

‘As the court stated in granting a preliminary injunction, Ordinary consumers do not interpret warnings in accordance with a complex web of statutes, regulations, and court decisions, and the most obvious reading of the Proposition 65 cancer warning is that exposure to glyphosate in fact causes cancer. A reasonable consumer may understand that if the warning says ‘known to cause cancer,’ there could be a small minority of studies or experts disputing whether the substance in fact causes cancer. However, a reasonable consumer would not understand that a substance is ‘known to cause cancer’ where only one health organization had found that the substance in question causes cancer and virtually all other government agencies and health organizations that have reviewed studies on the chemical had found there was no evidence that it caused cancer. Under these facts, the message that glyphosate is known to cause cancer is misleading at best.’

In August 2015, a California court threw out a suit filed by Public Interest Alliance LLC against nearly 100 cosmetics companies that allegedly exposed consumers to Prop 65-listed TiO₂ without providing warning. In that case, the plaintiff did not conduct its own air-sampling tests to determine whether defendants' products contained the respirable TiO₂ form listed under Prop 65.

The defendants did, showing that no captured TiO₂ particles released during their products' application fit the designation. (Also see "[TiO₂ Prop 65 Dismissal Offers Lessons, Renews Hope For Industry](#)" - HBW Insight, 31 Aug, 2015.)

Now Environmental Health Advocates is coming armed with its own testing. (Also see "[TiO₂ Still A California Prop 65 Target; EU Commission Returns To SCCS With New Safety Questions](#)" - HBW Insight, 11 Oct, 2022.) According to PCPC, private enforcers of Proposition 65 have contended that hundreds of cosmetic and personal-care products that disclose titanium dioxide as an ingredient also contain the listed form of TiO₂.

PCPC notes that TiO₂ is a US Food and Drug Administration-approved color additive for cosmetics, foods, including dietary supplements, and drugs, as well as a generally recognized as safe and effective (GRASE) UV filter for use in OTC sunscreen products. (Also see "[FDA's Proposed Order For Sunscreens, A First Under OTC Reforms, Reprises 2019 Proposed Rule](#)" - HBW Insight, 24 Sep, 2021.)

Nevertheless, as soon as IARC concluded in 2010 that TiO₂ is "possibly carcinogenic to humans" based on "sufficient evidence in experimental animals," that finding alone obliged OEHHA in September 2011 to list TiO₂ – when present as "airborne, unbound particles of respirable size" – as a substance known to the state to cause cancer, making it subject to warning requirements under Prop 65.

The data IARC considered in its assessment consisted of two rodent studies that PCPC says are widely deemed "unreliable and unacceptable." The group explains, "That is because they subjected the rats to conditions of 'lung overload' that are implausible in humans due to the unrealistically high quantities of airborne titanium dioxide used on the rats, the far greater surface area of human lungs, and the far greater capacity of humans, as opposed to rats, to clear their lungs."

Meanwhile, there is no reliable epidemiological evidence that inhaled titanium dioxide causes cancer in humans, the trade group says. "On the contrary, the overwhelming weight of evidence indicates that titanium dioxide is not carcinogenic to humans, even at the highest observed levels of exposure."

Thus, California's requirement to include Prop 65 warnings on products containing TiO₂ is a

First Amendment violation of the US Constitution that compels false, misleading, and highly controversial statements about TiO₂ and its potential health effects, PCPC says.

The group is likely to file next for a preliminary injunction to bar further suits from being filed against TiO₂-containing product marketers while the matter is being litigated.

The Prop 65 First Amendment challenges have the US legal community's attention. Attorneys at Steptoe & Johnson, LLP noted in a June 2020 [client alert](#), "If upheld by the Ninth Circuit, the [glyphosate] decision could be a turning point for the Proposition 65 program. In any event, Judge Schubbs's analysis regarding ripeness and the perils of false or misleading (i.e., excessive) warnings provides a foundation for additional challenges to the other warning requirements, particularly where there is controversial evidence regarding risk."