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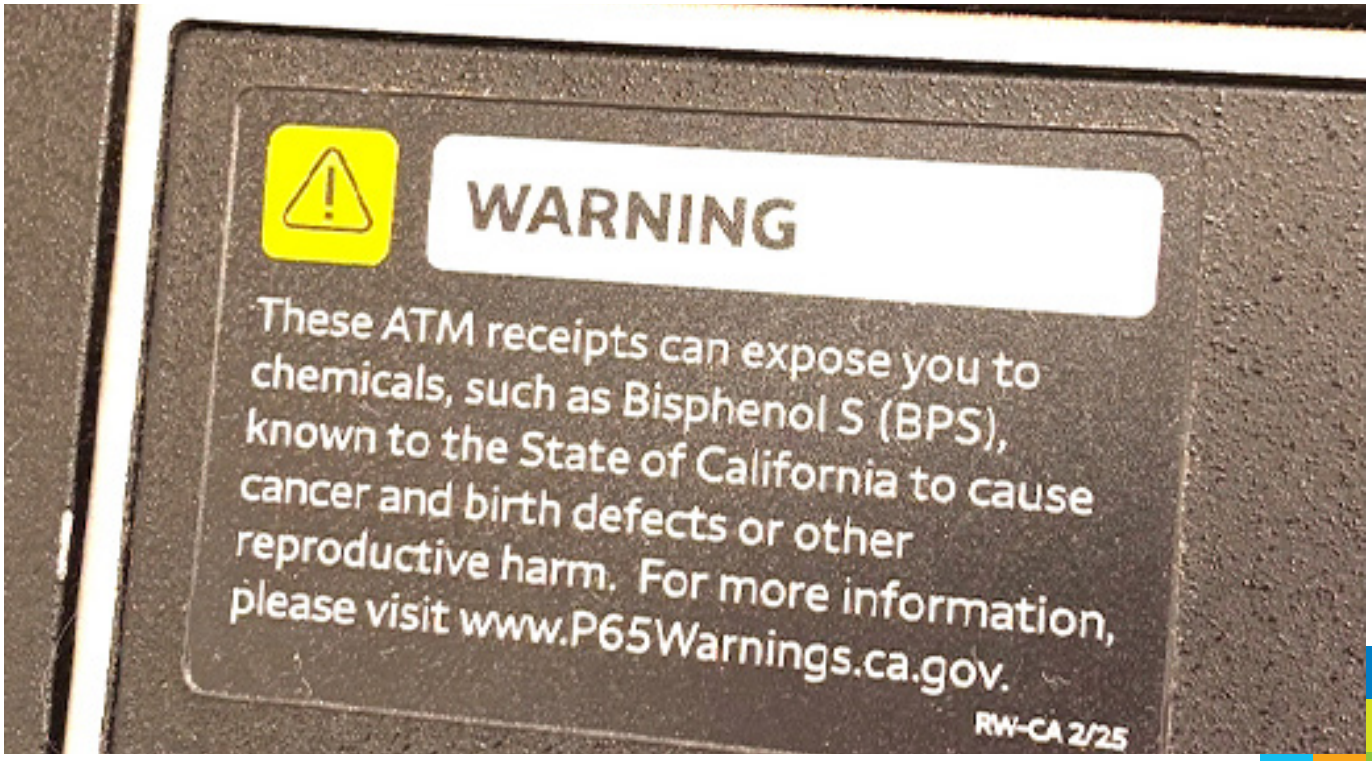

Experts foresee hurdles to California pursuing Prop 65 listing for bisphenol class

Industry must 'make the case that this is overly broad', observers say

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Industry attorneys have offered differing views about whether California regulators will have the scientific and legal backing to pursue a potential class-wide listing of p,p' -bisphenols under Proposition 65.

If enacted, such a listing could allow California's Office of Environmental Health Hazard Assessment (OEHHA) to ensure the public is warned about exposures to a range of bisphenols, a class sometimes cited as being prone to 'regrettable substitutions' between structurally similar substances.

At the same time, a class-based Prop 65 listing could also foment legal and scientific challenges, while widening the scope for private enforcement of a substance group that has already seen a recent uptick over businesses' alleged failures to provide warnings, industry experts told Chemical Watch News & Insight.

The varying viewpoints follow OEHHA's selection in October of p,p' -bisphenols and their ethers and esters for review by the state's Developmental and Reproductive Toxicant Identification Committee (DARTIC), which will meet to determine whether to recommend listing the substances as reproductive toxicants under Prop 65.

If pursued, the broad listing could apply to dozens of bisphenol substances and affect products across many sectors, including can liners, food containers, water bottles, medical devices, dental sealants and plastic goods.

Three bisphenols are already listed under Prop 65: bisphenol A (BPA) and bisphenol S (BPS) for reproductive and developmental toxicity, and tetrabromobisphenol A (TBBPA) for carcinogenicity.

A class-wide bisphenol listing could add dozens more substances to the state's right-to-know scheme, ushering in a requirement for companies to provide warnings when exposing individuals to any of the substances above a safe harbour level.

'Focus on the endpoint'

Maureen Gorsen, a partner at Sidley Austin, said there is precedent for OEHHA listing classes of substances, pointing

to the Prop 65 listings for PFOS and its salts and nickel and its soluble compounds.

"They just have to focus on the endpoint – like reproductive toxicity, which is the situation here – and whether there is enough evidence to support that this group or class presents a risk," she said.

Gorsen said she expects a listing to succeed, but it may not match the breadth of OEHHA's initial data request.

"People will bring evidence that some of the substances don't act the same as some of the other substances in this class, so they could narrow it," she said, noting OEHHA took that path to taper its nickel listing to focus only on the metal's soluble compounds.

"If the evidence is mixed, they could carve out a smaller grouping that tracks the evidence more closely," she said. "It'll be up to the people who are making and using [bisphenols] to make the case that this is overly broad."

Scientific disagreement has posed problems for Prop 65 listings in the past. In recent years, courts have invalidated warning requirements for glyphosate, titanium dioxide and acrylamide on the grounds that the Constitution only allows government-compelled speech that is "purely factual and uncontroversial".

Dennis Raglin, an attorney at Carlton Fields, pointed to OEHHA's call for human epidemiology data on bisphenols as a sign that the agency might be trying to address those concerns.

"OEHHA appears to be heeding the message from these three federal courts that a chemical with no human study and where agencies and studies disagree could lead to the [listing] being found unenforceable," he said.

'Substantial ambiguity'

Peter Coneski, a scientific adviser for K&L Gates, said he thinks OEHHA scoped the class broadly to "maximise the amount of information for review" by DARTIC.

Nonetheless, he is sceptical that a broad listing would hold up under a legal challenge.

Toxicological potency "can vary quite considerably even for chemicals within the same class", according to Dr Coneski. That means safe harbour limits need to be compound-specific, which would "justify listing chemicals on a compound-by-compound basis".

"I doubt that OEHHA would be able to list a broad grouping of chemicals without a significant amount of resistance," Dr Coneski said. "It would just make sense to list class members individually."

Will Wagner, an attorney at Greenberg Traurig, said class-based listings "could upend the regulatory structure of Prop 65 and further proliferate" enforcement actions.

"I suspect such listings would create substantial ambiguity that Prop 65 plaintiff lawyers would try to seize on," Wagner said. "Trying to list classes leads to confusion in the regulated community about what chemicals are in the class and how an exposure assessment should work."

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