

Triclosan: Proposition 65's Next BPA?

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On Sept. 2, 2016, the U.S. Food and Drug Administration issued a final rule banning the sale of over-the-counter antibacterial soaps containing certain chemicals. The rule comes amid growing concern among environmental health experts about the potential health effects of these chemicals. In issuing the rule, the FDA said industry had failed to prove the chemicals were safe to use over the long term or that they were more effective than simply using ordinary soap and water. Companies have a year to get the chemicals out of such products.



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The federal rule only applies, however, to consumer hand washes and soaps. Other common consumer products containing the chemicals remain unaffected by the rule. One of the most common of these chemicals, triclosan, is found in many other consumer products such as toothpaste, mouthwash, cosmetics, deodorants, kitchenware and office and school products. Triclosan is a suspected endocrine disruptor linked to reproductive and developmental harm.

While other products containing triclosan may not be affected by the federal ban, such products are unlikely to escape California's Proposition 65. Prop 65, a voter initiative passed as the Safe Drinking Water and Toxic Enforcement Act of 1986 (California Health & Safety Code Section 25249.5 et seq.) is intended to provide the public with notice about carcinogens and reproductive toxins that may be present in everyday products and exposure areas. Companies doing business in California realized long ago that it is a peculiar statute that requires their careful attention, particularly because private citizens can enforce it, thereby exposing businesses to "bounty hunter" plaintiffs who seek attorneys' fees and penalties.

With the recent federal ban, the widespread exposure of consumers to triclosan, and the growing evidence that triclosan may cause reproductive harm, and may even be linked to certain cancers, triclosan is likely to end up on the list of chemicals subject to Prop 65's warning requirements. This means every consumer product sold in California exposing consumers to triclosan will be required to be accompanied by a "clear and reasonable" warning of its potential reproductive toxicity and/or carcinogenic qualities if that exposure meets very low threshold levels.

What is Triclosan?

Triclosan is an ingredient added to many consumer products intended to reduce or prevent bacterial contamination and originally was used in the 1970s by surgeons to wash their hands before operations. Since that time, its use has expanded commercially and it is prevalent in soaps, toothpastes and many

other consumer products regulated by the FDA. It also can be found in clothing, kitchenware, furniture and toys — products not regulated by the FDA.

The U.S. Environmental Protection Agency also regulates triclosan as a registered pesticide. According to the EPA's website, it acknowledges the rapidly developing scientific database for triclosan and notes that it has been collaborating with the FDA on research projects that will help both agencies to better characterize the endocrine-related effects of triclosan, including toxicological effects, human relevance and the doses at which they occur to determine if levels of human exposure are safe.[1]

Triclosan's efficacy as an antimicrobial agent, the risk of bacterial resistance and its possible role in disrupted hormonal development has long been controversial. In 2010, the Natural Resources Defense Council filed suit against the FDA, claiming that antibacterial soaps contain toxic chemicals that put consumers at risk, and that FDA had failed to move forward on a decades-old proposal to regulate them.

The FDA finally proposed a rule in 2013 as a result of the NRDC suit, citing data suggesting that long-term exposure to these antibacterial compounds could pose health risks, such as bacterial resistance or hormonal effects. In issuing the final rule this past September, the agency said industry had failed to provide the necessary data to establish the safety and effectiveness of the chemicals. Indeed, since the FDA's proposed rulemaking in 2013, manufacturers already have started to phase out the use of certain active ingredients in antibacterial washes, including triclosan.

Triclosan and Proposition 65

Prop 65 requires the state of California to publish and revise, at least once each year, a list of chemicals known to the state to cause cancer or reproductive harm. The law also requires businesses to provide "clear and reasonable" warnings prior to knowingly and intentionally exposing persons in California to any of the over 800 chemicals on the list where such exposure exceeds a specified threshold level. Providing Prop 65 warnings can be burdensome to many companies, and California just adopted a new regulation on Aug. 30, 2016, which sets forth even more stringent and specific requirements a warning must satisfy to be deemed "clear and reasonable" under the law. Those new requirements go into effect Aug. 30, 2018. If a chemical is not on the list, however, Prop 65 does not apply.

Triclosan is not on the Prop 65 list. Not yet, anyway.

Actually, triclosan already has been under the Prop 65 microscope once, for its possible carcinogenic effects. In May 2009, the state reviewed available scientific literature regarding the potential cancer-causing effect of triclosan and 37 other chemicals that had data suggesting that they cause cancer. Following that 2009 review, the state decided that the data at the time did not warrant advancing triclosan to the next step of the listing process.

The Prop 65 Listing Process

One of the mechanisms by which a chemical is placed on the list is a finding by the "state's qualified experts" that a chemical "has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity" (Health & Safety Code Section 25249.8(b)). To that end, the state agency responsible for listing chemicals, the Office of Environmental Health Hazard Assessment (OEHHA), has established a Science Advisory Board, which includes two committees of independent scientists and health professionals — the Carcinogen Identification Committee (CIC) and the Developmental and Reproductive Toxicant Identification Committee (DART IC)

— to act as its qualified experts.

A chemical may also be added to the list if OEHHA determines that an authoritative body identified by the Science Advisory Board formally has identified the chemical as causing cancer or reproductive harm or if the OEHHA determines that a state or federal agency formally has required the chemical to be identified or labeled as causing cancer or reproductive toxicity.

As to the first listing mechanism, OEHHA has developed a process to identify and prioritize chemicals for evaluation by the CIC and DART IC.[2] In accordance with that procedure, on May 29, 2009, the CIC and OEHHA staff met so that the CIC could provide OEHHA with advice on the prioritization of triclosan and the other chemicals. The chemicals were not being proposed for listing at that time; rather, the purpose of the meeting was to determine which chemicals should proceed to the next step of the listing process, i.e., the development of hazard identification materials by OEHHA followed by the consideration for listing by the CIC at a future meeting. Triclosan was categorized as “low” priority and did not advance to the next stage of the listing process. The low prioritization was based on data existing at the time, which did not support a higher prioritization of triclosan.[3]

There is a growing body of data, however, which suggests that triclosan can cause reproductive harm in animals, and many health experts warn that the effect could be the same in humans. In 2014, as the FDA was gathering information and considering whether to ban the antibacterial compounds, scientists reported that urine and umbilical cord blood sampling indicated many pregnant women and their fetuses are being exposed to these substances. Indeed, one study suggests that triclosan may disrupt boys’ growth during their fetal period and first years of life.

In light of this, industry should not be surprised to see triclosan come to the forefront of OEHHA’s attention in the near future. As noted, the Prop 65 chemical list must be revised and republished in light of additional knowledge at least once per year.[4]

The multistep prioritization process described above is but one method by which a chemical can reach the CIC or DART IC for consideration. As has always been the case, the director of OEHHA at his or her discretion may decide to abbreviate or modify the process. For example, a member of the public or a committee member may petition OEHHA to abbreviate the process to respond to new information or an emerging public health issue. Following consultation by the director with the appropriate committee chair, a chemical may then be placed on the agenda for discussion at the next scheduled committee meeting. The CIC and DART IC must meet not less than once in every calendar year.[5]

While triclosan has been on the radar of many health professionals and consumer rights advocates for decades, the federal ban and recent scientific studies indicating potential reproductive harm certainly qualifies triclosan as an emerging health issue. Accordingly, it would not be surprising to see triclosan as the subject of a petition to abbreviate the listing process.[6]

Many companies have stopped using triclosan in their products over the last several years. However, if triclosan is listed as a chemical known to the state of California to cause reproductive harm (or cancer), then any products continuing to expose California consumers to sufficient levels of triclosan will be required to be accompanied by a “clear and reasonable” warning informing such consumers of the exposure and possible associated harm. Based on the way OEHHA views similar chemicals, this may happen sooner rather than later.

Another BPA?

Triclosan is an organic compound categorized as a type of phenol. Another widely-used phenol, bisphenol A, was the subject of a controversial and disputed listing by OEHHA in recent years.

On May 11, 2015, BPA was added to the Prop 65 list of chemicals known to the state to cause reproductive toxicity. But that was not the first time OEHHA had listed BPA and its listing has been a litigious endeavor. DART IC unanimously voted to list BPA as a reproductive toxicant several years ago. OEHHA then issued a notice of intent to list BPA in January 2013.

While this decision was pending, the American Chemistry Counsel (ACC) filed a lawsuit in March of that year seeking to block OEHHA from including BPA on the Prop 65 list, but OEHHA nevertheless moved forward and listed BPA on April 11, 2013. ACC opposed the listing based in part on the FDA's 2012 refusal to prohibit BPA in food packaging and claimed OEHHA had abused its discretion in listing the chemical. ACC obtained an injunction on April 19, 2013, forcing OEHHA to remove BPA from the Prop 65 list. The injunction was in effect until December 2014, when the court ultimately held that OEHHA did not abuse its discretion.

Once the court process concluded, OEHHA set its sights on BPA once again and formally listed it as a chemical subject to Prop 65 on May 11, 2015. That gave companies only 12 months to comply with Prop 65's "clear and reasonable" warning requirement.

OEHHA's decision to list BPA remained controversial because health experts, including the FDA and European Food Safety Authority, consistently have concluded through research that exposure to BPA is safe in typical dosage levels. (The FDA did ban BPA from baby bottles and sippy cups in 2012, a move it said it took as a precaution.) In fact, per its website, FDA's current perspective, based on its most recent safety assessment, is that BPA is safe at the current levels occurring in foods.[7] Based on FDA's ongoing safety review of scientific evidence, the available information continues to support the safety of BPA for the currently approved uses in food containers and packaging.

Nevertheless, concluding that BPA posed a significant threat to consumers, OEHHA listed BPA under Prop 65. It should not come as a shock if triclosan underwent a similar process and received similar treatment from OEHHA despite the current lack of consensus in the scientific community on its human health effects.

Conclusion

The ubiquitous presence of triclosan in consumer products means that a person's exposure to the chemical can be constant. Aside from FDA and industry, state policymakers have taken notice of the growing evidence of triclosan's potential health effects. In light of this, manufacturers and retailers of consumer products containing the chemical who do business in California should keep a watchful eye on OEHHA's approach to triclosan. In the meantime, manufacturers may be wise to consider removing triclosan from their products entirely.

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information purposes and is not intended to be and should not be taken as legal advice.

[1] See https://archive.epa.gov/pesticides/reregistration/web/html/triclosan_fs.html.

[2] See OEHHA's December 2004 document titled "Process for Prioritizing Chemicals for Consideration Under Proposition 65 by the 'State's Qualified Experts,'" which describes the process used to identify chemicals for evaluation by the CIC and DART IC. The document is designed to ensure that the efforts of those committees are focused on chemicals that may pose significant hazards to Californians. The December 2004 document is available at <http://oehha.ca.gov/media/downloads/proposition-65/document/finalpriordoc.pdf>.

[3] A summary of the May 29, 2009, meeting, as well as a copy of the transcript, is available at <http://oehha.ca.gov/proposition-65/events/may-29-2009-carcinogen-identification-committee-meeting>.

[4] Cal. Health & Safety Code § 25249.8(a).

[5] Cal. Code Regs. Tit. 27, § 25302(c).

[6] California would not be the first state to tackle triclosan. In 2014, Minnesota became the first state to prohibit the use of triclosan in most retail consumer hygiene products. The exceptions to the ban are individual products that have received approval from the FDA for consumer use. That law will go into effect Jan. 1, 2017.

[7] See <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm>.