

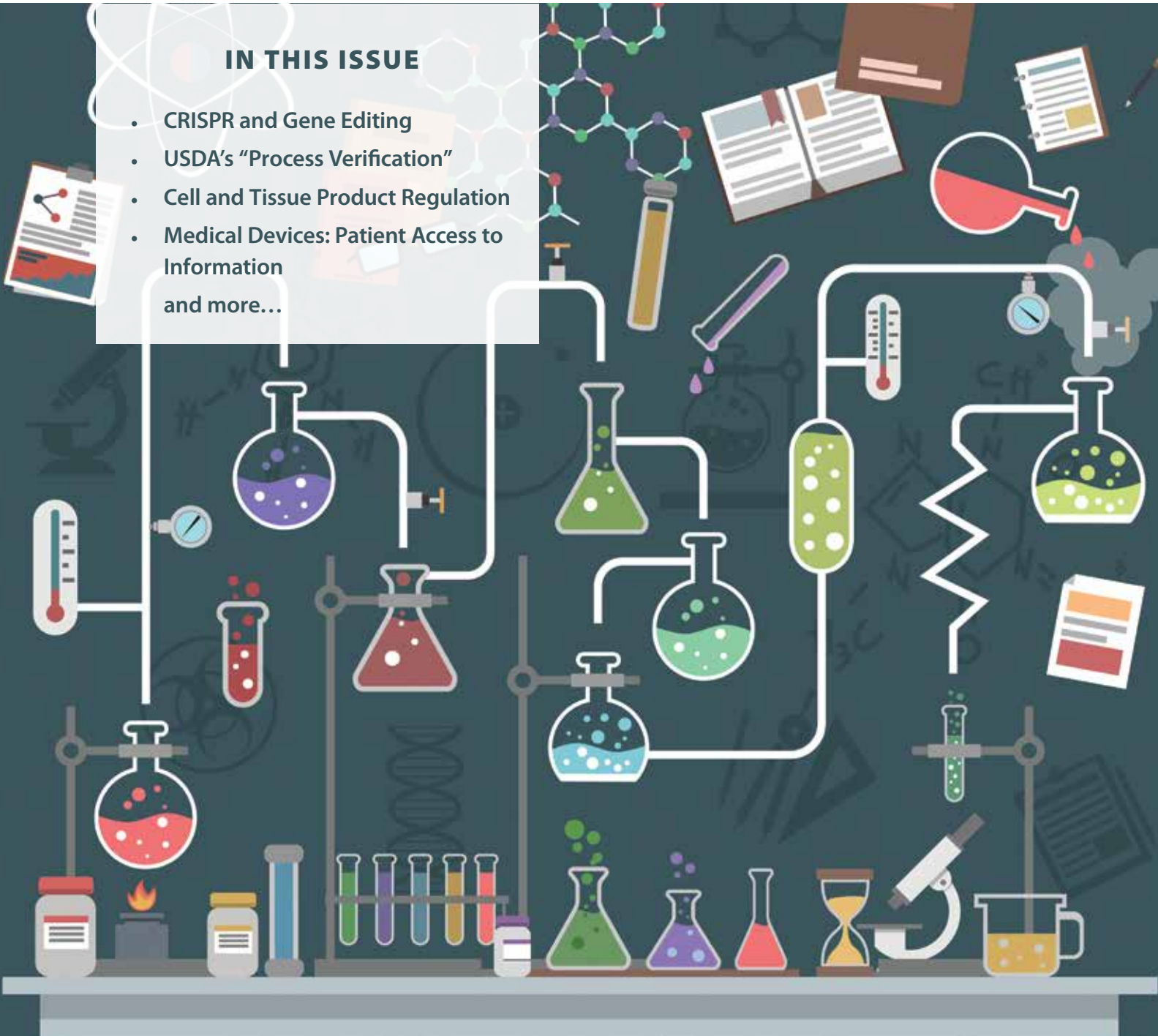
UPDATE

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Shelter from the Gathering Storm— Complying with the BPA Prop 65 Warning Requirements

by *Xin Tao and Martin J. Hahn*

Bisphenol A, or BPA, is an industrial chemical that has been safely used for decades in the manufacturing of food packaging materials such as epoxy resins on metal cans and polycarbonate containers. The BPA molecule has a structure similar to that of estrogen, and it has made headlines in recent years for its allegedly adverse estrogenic effects. Despite the U.S. Food and Drug Administration’s (FDA) repeated assurance of BPA’s safety for use in food packaging,¹ BPA has become the false poster child for “bad chemicals” and has been shunned by consumers.

Effective May 11, 2016, California’s Office of Environmental Health Hazard Assessment (OEHHA) started requiring warnings for consumer products containing BPA under the

Safe Drinking Water and Toxic Enforcement Act of 1986 (also known as Proposition 65 or Prop 65).² OEHHA added BPA to Prop 65 as a chemical known to cause reproductive toxicity.³ Under Prop 65, businesses are required to provide a “clear and reasonable” warning before knowingly and intentionally exposing anyone in California to a listed chemical.⁴ For consumer products containing a reproductive toxicant, OEHHA’s regulations provide a model warning statement: “This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.”⁵ Importantly, products are exempt from the Prop 65 warning requirements if the exposure to a listed chemical is below the safe harbor level (for reproductive toxicants, also known as a Maximum Allowable Dose Level or MADL).⁶



Compliance Strategies for Prop 65 Warning Requirements

There should be three steps in a company's decision-making process for complying with the BPA Prop 65 warning requirements. First, a company that sells food products packaged in metal cans coated with epoxy resin or polycarbonate containers should decide whether it can find an alternative to BPA. Indeed, once a chemical is listed under Prop 65, most manufacturers will start phasing out its use. However, the chemical industry has been struggling to find an alternative to BPA due to its high versatility and prevalent use.⁷ A recent report published by a collaboration of consumer interest groups led by the Breast Cancer Fund found that 67% of the food cans tested (129 out of 192) still contain a BPA-based epoxy resin in the body or the lid.⁸ To further complicate matters, it is reported that common BPA alternatives such as Bisphenol S (BPS) and Bisphenol F (BPF) might also have the same allegedly adverse estrogenic effects as BPA.⁹

Second, if a company has not found an alternative to BPA and its products are marketed in California, it should determine whether its products expose consumers to BPA at levels that would trigger the Prop 65 warning requirements. Analytical testing of the BPA levels in the products is typically required for such an assessment. While OEHHA established an MADL of BPA at 3 micrograms (μg) per day for dermal exposure from solid materials,¹⁰ as of this writing, OEHHA has not developed an MADL for oral BPA exposure. It is unlikely that OEHHA will establish an oral safe harbor for BPA until 2017 or 2018 when additional safety data on BPA become available. In the absence of an OEHHA oral safe harbor, a company can determine whether it is appropriate to develop its own safe harbor level based on sound toxicology principles. The California regulations provide companies with the ability to calculate a safe harbor.¹¹ In instances when the data show the listed substance, which is known to the state of California to cause reproductive toxicity, results in an exposure that is more than 1,000 times less than BPA's no observable adverse effect level, the company

can conclude no warning is required.¹² A company that takes such a position, however, does so with the risk that the courts in California could interpret the safe harbor for BPA under Prop 65 differently.

Finally, a company could opt to use the OEHHA emergency regulation that allows the temporary use of a standard point-of-sale warning message for BPA exposures from canned and bottled foods and beverages.¹³ Specifically, under the emergency regulation, the Warning Sign shall contain the following:¹⁴

“WARNING: Many cans containing foods and beverages sold here have epoxy linings used to avoid microbial contamination and extend shelf life. Lids on jars and caps on bottles may also have epoxy linings. Some of these linings can leach small amounts of bisphenol A (BPA) into the food or beverage. BPA is a chemical known to the State of California to cause harm to the female reproductive system. For more information go to: www.P65Warnings.ca.gov/BPA.”

While many companies may be tempted to simply adopt the above Warning Signs on BPA instead of conducting their own safe harbor assessment, it is important to note that the emergency regulation will expire after 180 days. After that, OEHHA plans to adopt the regulation as an interim measure for a one-year period. OEHHA believes this time period is sufficient to ensure an orderly transition to providing more product-specific warnings for BPA exposures and for companies to discontinue the use of BPA. When the interim measure lapses, OEHHA likely will expect companies to have switched to packaging that does not contain BPA or to warn California residents about the presence of BPA in that particular product. It also remains to be seen whether OEHHA will establish an oral safe harbor before or after the interim regulation expires, we suspect it would be the latter.

One additional complexity presented by the emergency regulation is that the list of products covered by the warning



Xin Tao is an associate at Hogan Lovells LLP. With a working knowledge of regulatory requirements and a strong understanding of life science, he works closely with clients in the food and drug industry to navigate the evolving federal and state regulatory environments and also develop innovative regulatory compliance strategies.



Martin J. Hahn is a partner at Hogan Lovells LLP. He uses his background in food technology and his comprehensive understanding of the laws governing the food industry to navigate clients through the myriad regulatory and business issues impacting the industry from farm to table.

has been published. Once the regulation expires, the state and “bounty hunters” will have a roadmap of each of the foods that contain BPA in their packaging and may decide to focus initially on these products if they do not bear the warning.¹⁵

Also, the emergency regulation is only applicable to canned and bottled foods and beverages that are offered for retail sale. Restaurants and other food service institutions cannot rely on the emergency regulation for compliance, and their products are subject to the general warning requirements found in the Prop 65 regulations. Specifically, the following Warning Sign can be used for food (other than alcoholic beverages) sold, served, or otherwise provided in food facilities, including restaurants:¹⁶

“WARNING: Chemicals known to the State of California to cause cancer, or birth defects or other reproductive harm may be present in foods or beverages sold or served here.”

“Non-BPA” Claim Risks and Mitigation Strategies

Responding to growing consumer preference for BPA-alternatives, food companies are also increasingly interested in using “non-BPA” types of claims on their products. BPA is omnipresent in the environment. As such, it would be prudent for a company to avoid using claims such as “BPA-free” because the product may unavoidably contain some trace amounts of BPA from the environment. Indeed, a report published by Consumer Reports found trace levels of BPA even in some cans labeled as “BPA-free.”¹⁷ A “non-BPA” claim, on the other hand, implies that BPA is not added and does not explicitly state that no BPA is present. Nonetheless, there are some regulatory and litigation risks associated with “non-BPA” claims. The level of risk will largely depend on the nature of the “non-BPA” coatings, which can fall into three categories: (1) “non-BPA” coating (e.g., vinyl coating); (2) epoxy resin using BPA analogs such as BPS and BPF; and (3) barrier coating (e.g., polyester coating) separating the BPA-containing epoxy coating from the food product.

Coatings such as a vinyl coating that can replace the BPA-containing epoxy resin are the most defensible materials to use for a “non-BPA” claim. The potential level of BPA present in this type of coating will be no more than that which would be found as an environmental trace contaminant. Also, BPA is not intentionally used in manufacturing the food packaging materials. To further substantiate the claim and mitigate the

risks, companies are encouraged to obtain a certificate of analysis or assurance letter from the packaging material suppliers that the can liners are formulated with alternative coatings that do not contain BPA or BPA analogs.

Epoxy resins using BPS and BPF have a higher risk profile than the non-BPA coatings. This is because these materials are reported to have the same allegedly adverse estrogenic effects associated with BPA. As such, a “non-BPA” claim may be challenged on the basis that it is potentially misleading to consumers who are trying to avoid exposure to BPA for any safety concerns. The risk can be mitigated if lower amounts of BPS and BPF, as compared to BPA, are used or the packaging supplier can provide scientific evidence or data supporting BPS or BPF’s safety. It also is possible that BPS and BPF may suffer the same fate as BPA and also be criticized for their use in packaging.

Using a “non-BPA” claim on a product that has the BPA-containing epoxy resin under a separate barrier coating presents the highest risks of the three approaches discussed in this article. In this case, BPA is intentionally added to the packaging, and there is also a theoretical risk that the BPA will leach into the food through the barrier coating. Consumers may find the claim misleading because the “non-BPA” claim could be viewed as implying there is no BPA in the packaging while it is actually present—albeit not in contact with food. If the claim is made, it would be advisable to disclose that the packaging materials actually contain a non-food-contact BPA layer. Companies that are interested in making a “non-BPA” claim on these types of products should work closely with their legal and regulatory teams to explore the merits and risks of the claim and disclosures that could mitigate the risk.

A Gathering Storm of BPA Litigation

Companies selling BPA-containing food products in California are vulnerable to private litigants or “bounty hunters” who can bring private lawsuits to enforce the Prop 65 warning requirements. Prop 65 has been a thriving business for bounty hunters. Violations of Prop 65 are subject to civil penalties of up to \$2,500 per day per violation.¹⁸ Further, Prop 65 allocates 25 percent of any assessed penalty to a successful plaintiff.¹⁹ These provisions offer a strong monetary incentive for Prop 65 lawsuits. The potential of significant civil penalties also helps “bounty hunters” coerce businesses into settlements with demand letters.

A “bounty hunter” must notify the potential defendant and state prosecutors of the alleged violation and its intent to sue 60 days before a suit may be filed.²⁰ The first 60-day notice

of violation related to BPA was recently filed by Center for Environmental Health (CEH), a well-known Prop 65 “bounty hunter.” According to the Notice, which was filed on June 14, CEH claimed that Del Taco Restaurants, Inc., Del Taco LLC, and Grewal Superfoods, Inc. violated California’s Prop 65 by using thermal receipt paper that exposed consumers to BPA without providing a clear and reasonable warning.²¹ CEH further claimed that the consumers were exposed to BPA by both dermal absorption directly through the skin and ingestion via hand-to-mouth contact after consumers handled the receipt. On June 27, CEH filed another 60-day notice against DS Services of America, Inc. and Home Depot U.S.A., Inc. for violating Prop 65 by exposing consumers to BPA through bottled water in plastic bottles. This time, CEH claimed that the consumer exposure is through direct ingestion when consumers drink the water stored in polycarbonate plastic bottles such as Alhambra 5-Gallon Bottled Water.²²

The recent effective date of the BPA warning requirements under Prop 65 will present many challenges to the industry, particularly once the interim regulation expires and companies are forced to either find an alternative polymer, determine if their products are within a safe harbor, or label. Companies should assess the alternative technologies that are available and carefully consider the risks associated with marketing claims such as “non-BPA” or “BPA free.” ▲

1. FDA, “Bisphenol A (BPA): Use in Food Contact Application,” <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm>.
2. OEHHA, “Notice of Emergency Action to Amend Section 25603.3 Title 27, California Code of Regulations Warnings for Exposures to Bisphenol A From Canned and Bottled Foods and Beverages,” <http://oehha.ca.gov/proposition-65/crnrr/notice-emergency-action-amend-section-256033-title-27-california-code>.
3. OEHHA, “Bisphenol-A Listed as Known to the State of California to Cause Reproductive Toxicity,” <http://oehha.ca.gov/proposition-65/crnrr/bisphenol-listed-known-state-california-cause-reproductive-toxicity>.
4. Cal. Health & Safety Code § 25249.6.
5. 27 CCR § 25603.2.
6. 27 CCR § 25801.
7. Bomgardner, Melody M. “No clear winner in race to find non-BPA can linings.” *Chemical Engineering News* 91.6 (2013): 24-25.
8. Breast Cancer Fund et.al, “Buyer Beware – Toxic BPA and regrettable substitutes found in the linings of canned foods” (2016).
9. Rochester, Johanna R., and Ashley L. Bolden. “Bisphenol S and F: a systematic review and comparison of the hormonal activity of bisphenol A substitutes.” *Environmental Health Perspectives (Online)* 123.7 (2015): 643.
10. OEHHA, “Amendment to Section 25805, Maximum Allowable Dose Level - Bisphenol A (Dermal Exposure from Solid Materials),” <http://oehha.ca.gov/proposition-65/crnrr/amendment-section-25805-maximum-allowable-dose-level-bisphenol-dermal-exposure>.
11. *See supra* note 6.
12. Cal. Health & Safety Code § 25249.10.
13. *See supra* note 2.
14. 27 CCR § 25603.3(g).
15. Compliance with Prop 65 may be enforced by the state Attorney General and by private litigants, often called “bounty hunters.”
16. 27 CCR § 25603.3(a).
17. Consumer Reports, “Concern Over Canned Foods,” (2009), <http://www.consumerreports.org/cro/2012/05/concern-over-canned-foods/index.htm>.
18. Cal. Health & Safety Code § 25249.7.
19. *See id.*
20. *See id.*
21. Notice of Violation, “Bisphenol A in Thermal Receipt Paper,” <https://oag.ca.gov/system/files/prop65/notices/2016-00570.pdf?> A revised notice of violation was filed on June 27, <https://oag.ca.gov/system/files/prop65/notices/2016-00623.pdf?>
22. Notice of Violation, “Bisphenol A in Bottled Water in Polycarbonate Plastic Bottles for Use in Water Coolers,” <https://oag.ca.gov/system/files/prop65/notices/2016-00622.pdf?>