States Pass New Chemical Laws and Regulations

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Six 60-Day Notices of Violation Issued for Hexavalent Chromium Found on Leather Products

By LisaLisa | States Pass New Chemical Laws and Regulations

Six 60-day notices of violation have recently been issued for the use of hexavalent chromium in leather goods. The notices serve as warnings of the intent to start legal proceedings.

Hexavalent chromium (Cr (VI)) was listed in 1987 under California Proposition 65 (Prop 65) as a toxic chemical that causes birth defects and other reproductive problems and cancer.

The six Notices of Violation were issued because of consumer exposure to Cr (VI) in a variety of leather products used in gloves for work and gardening, driving and fashion, golf and sports.

Humans can be exposed to Cr (VI) through hand to mouth contact after touching, wearing, or handling the leather products. Exposure can also be possible through dermal absorption. Health problems associated with exposure to Cr (VI) include allergies, throat, nasal, or respiratory irritation.

Cr (VI) is often unintentionally formed as an unwanted tanning process by-product in leather manufacturing, while in storage and shipment of leather products.

The Safe Drinking Water and Toxic Enforcement Act of 1986 or California Proposition 65 (Prop 65), became law in November 1986. The law is the basis why there is a Prop 65 list of approximately 900 harmful substances.

Businesses based in California are required to provide a Prop 65 Warning or a clear and reasonable warning on products that can expose anyone to a substance above its specified safe level.

OAL Approves OEHHA's Coffee Exemption

By LisaLisa | States Pass New Chemical Laws and Regulations

By A. J. Esposito

On June 3, 2019, the California Office of Administrative Law approved a regulation adopted by the California Environmental Office of Health Hazard Assessment (OEHHA) exempting chemicals in coffee from Prop 65's warning requirement. The regulation, which takes effect on October 1, 2019, provides:
Exposures to chemicals in coffee, listed on or before March 15, 2019 as known to the state to cause cancer, that are created by and inherent in the processes of roasting coffee beans or brewing coffee do not pose a significant risk of cancer.
While the adoption of the regulation would seem to end the ongoing controversy about whether Prop 65 warnings are required for acrylamide in coffee, and appear to be very good news for those who make and sell coffee, the adoption of the new regulation still has to address several loose ends from the findings and rulings of the Eight years of coffee litigation.
Chief among these findings were rulings made by brought by the Council for Education and Research on Toxics (CERT) in which Los Angeles Superior Court Judge Elihu Berle found that coffee roasters and retailers failed to demonstrate that the levels of acrylamide – a chemical formed when coffee beans are roasted – did not pose a significant risk of cancer.

Another critical loose end was that in September 2018, CERT filed a separate action against OEHHA, seeking to have the proposed regulation deemed invalid, for a variety of reasons. The case was originally assigned to Judge Berle, but OEHHA requested reassignment to another judge because Berle's original decision was based on much of the same evidence as OEHHA's regulation, but, would be determined under a different standard. The replacement judge, Carolyn Kuhl, stayed the litigation until the regulation was finalized, and then decided to stay the action entirely to let Judge Berle determine the validity of the regulation in the enforcement case. On June 5, 2019, OEHHA filed a writ petition in the Court of Appeal, seeking to have Judge Kuhl ordered to lift the stay and determine the validity of the regulation. CERT has yet to file a response to the writ petition.

In September 2018, Judge Berle rejected the coffee companies' request to stay the litigation during the rulemaking (as well as their first amendment argument that compelling a warning that coffee caused cancer was controversial and factually inaccurate in light of the overwhelming evidence in the June 2018 monograph published by the International Agency for Research on Cancer (IARC) on which OEHHA relied for its regulation), and set an October 15, 2018 trial date for the CERT's request for civil penalties and an injunction. The Friday before trial was to start, October 12, 2018, the California Court of Appeal granted the companies' request for a stay, which has been in effect since that date.
Meanwhile, on September 7, 2018, CERT filed a separate action against OEHHA, seeking to have the

proposed regulation deemed invalid, for a variety of reasons. The case was originally assigned to Judge Berle, but OEHHA requested reassignment to another judge due to the fact that his original decision was based on much of the same evidence as OEHHA's regulation, but would be determined under a different standard. The new judge, Carolyn Kuhl, stayed the litigation until the regulation was finalized, and then decided to stay the action entirely to let Judge Berle determine the validity of the regulation in the enforcement case. On June 5, 2019, OEHHA filed a writ petition in the Court of Appeal, seeking to have Judge Kuhl ordered to lift the stay and determine the validity of the regulation. CERT has yet to file a response to the writ petition.

On May 31, CERT asked the Court of Appeal to allow Judge Berle to resume as the presiding judge in the case so that the parties can litigate whether the regulation applies to it, and if so whether the regulation is valid. The coffee roaster defendants have asked the appellate court to maintain the stay so that the validity of the regulation can be decided in the case in which OEHHA is a party – the case currently stayed by Judge Kuhl. As of June,10 2019, the Court of Appeal has yet to take any action on either request.

There are a number of issues that remain unresolved, and it is quite likely that these issues will take eventually be resolved in the Court of Appeals

Among the issues that must be sorted out is whether Judge Berle or Judge Kuhl will decide whether the regulation is valid.

In its writ petition, OEHHA contends that it is not a party to CERT's enforcement litigation, and it will not be bound by any decision Judge Berle makes. OEHHA contends that it should not be required to litigate the validity of the regulation before a judge it has challenged, who has already made decisions on some of the same evidence, with a different legal standard (the proof necessary for a "no significant risk" defense to a Prop 65 enforcement action vs. the proof necessary to show that a regulation is invalid because it is "arbitrary and capricious").

The following issues remain to be decided:

Is the regulation valid?

CERT has raised a litany of challenges to the regulation. OEHHA's position is that its regulation is eminently justified by the science, as it told the Court of Appeal in its writ petition:

As the Administrative Record supporting OEHHA's Regulation will show, although coffee contains chemicals that have been identified as carcinogens in some contexts, there is overwhelming scientific evidence that consumption of coffee poses no increased risk of cancer; to the contrary, consumption of coffee may lower the risk of several types of cancer. (Emphasis added.)

Does the regulation apply to the existing litigation?

While it may be obvious that if the regulation applies to the litigation the case must be dismissed. However, CERT contends that because the regulation was not adopted until after the court found liability, it cannot be retroactively applied. CERT also argues that the

Everyone recognizes that, if the regulation applies to the litigation, the case must be dismissed. Not surprisingly, CERT takes the position that because the regulation was not adopted until after the court found liability, it cannot be retroactively applied. CERT also argues that the defendants did not include the regulation in their affirmative defenses, so they cannot rely on it.

The defense has argued that because Proposition 65 is a statutory remedy, and because OEHHA is authorized to develop regulations to implement Prop 65 (including how the no significant risk defense is established), any changes that are adopted before final judgment are applicable to pending litigation under the "statutory repeal" rule. The defendants also note that their answers all raised the no significant risk defense, and that this new regulation is simply a specific implementation of that defense, such that no amendment of their answers is necessary.

Will conflict preemption arisen become a factor in the case?

Recently, the U.S. FDA supported the proposed regulation. In a statement, FDA Commission Scott Gottlieb, M.D., stated:

We've taken this position because we too have carefully reviewed the most current research on coffee and cancer, and it does not support a cancer warning for coffee. In fact, as our letter to California states, such a

warning could mislead consumers to believe that drinking coffee could be dangerous to their health when it actually could provide health benefits. Misleading labeling on food violates the Federal Food, Drug, and Cosmetic Act. No state law can require food to bear a warning that violates federal law.

While Prop 65 has avoided many preemption challenges, it has been successfully challenged where its warnings are at odds with federal agencies' positions on product labeling, most famously when the California Supreme Court upheld a finding that Prop 65 warnings for nicotine replacement therapy products was preempted by FDA's rejection of the Prop 65 warning language in Dowhal v. Smithkline Beecham Consumer Healthcare, 32 Cal. 4th 910 (2004).

If the regulation does not dispose of the litigation, it is likely that the defense will assert that imposing a Proposition 65 warning for coffee will irreconcilably conflict with federal law, given FDA's position that such a warning could mislead consumers.

Don't expect the conclusion of this litigation anytime soon. The Coffee trial will eventually be resolved in an appellate court, most likely by a bunch of geriatric litigators in their late 80s.

Solvent industry Petitions Court for Review of Methylene Chloride Ban

By LisaLisa | States Pass New Chemical Laws and Regulations

The Halogenated Solvents Industry Alliance (HSIA) has sued for the review of the US EPA's final rule that prohibits consumer use of paint removers containing dichloromethane (DCM) or methylene chloride.

The final rule in TSCA section 6 issued in March, applies to the import, manufacture, processing, and distribution to consumers of the products. Commercial uses are not covered by the ban but the agency is soliciting feedback on a possible workplace training program for workers exposed to the chemical.

It is not specified in HSIA's complaint what aspects of the rule is challenged by the group. However, solvents group's lawyer, Squire Patton Boggs partner Caffey Norman, said that HSIA's chief concern is EPA definition of 'retailers'

The rule states that "any distributor with at least one consumer end-user customer is considered a retailer."

According to this definition, it appears to have the "unintended consequence" of identifying as "retailer" the hardware stores and other outlets where small businesses historically purchase their paint removers.

So, based on the rule's definition, a warehouse distributor that has sold a chemical product to a consumer would be considered a 'retailer.' That warehouse distributor would be barred from supplying its commercial users with methylene chloride-containing products.

The presumably unintended consequence is that chemical products distributors will not sell to consumers or will stop selling methylene chloride paint strippers.

According to the HSIA, the ban "in effect eliminates access by small commercial users such as painting contractors, artisans, antique restorers, and the like who are not in a position to purchase the product in bulk quantities."

The HSIA filed the case on May 24 at the US Court of Appeals for the DC Circuit. In April, a coalition of labor groups and NGOs filed a separate lawsuit because the commercial use of the chemical was not included in the rule.

It’s likely that the petitions will be consolidated by the courts into a single case.

Maine Governor Signs Resolution On Toxic Workplace Chemicals

By LisaLisa | States Pass New Chemical Laws and Regulations

Maine Governor Signs Resolution On Toxic Workplace Chemicals

On June 5, Maine's Governor Janet Mills signed into law a bill that requires the state's Department of Labor to develop a framework for identifying hazardous chemicals in the workplace and replacing them with safer alternatives.

The bill, Legislative Document (LD) 1017, passed the state's House and Senate on May 28 and was signed by the Governor the next day. The bill respectively requires collaboration with "interested parties", as well as employees and employers in industries that often use hazardous substances.

The new law further directs the Department of Labor to submit a report of its findings to the legislature's Joint Standing Committee on Labor and Housing by December 20. The findings will most likely inform future legislative bills on hazardous chemicals and their alternatives  .

Retailers Voluntarily Withdraw Makeup that Tested Positive in Asbestos Tests

By LisaLisa | States Pass New Chemical Laws and Regulations

Retailers Claire's Stores and Beauty Plus Global have started the voluntary recall of two makeup products after the advisory from the US Food and Drug Administration that notified them they tested positive for asbestos.

The two products that tested positive for asbestos were the Chinese-based cosmetics company's Beauty Plus Global Contour Effects Palette 2 and Claire's JoJo Siwa Makeup Set which is a makeup kit formulated for young girls and teens.

The FDA advised current users of the two recalled products to stop using them.

Exposure to asbestos dust is known to cause serious health conditions such as mesothelioma and lung cancer decades later.

The asbestos contamination comes from talc used in the makeup products. Talc in its natural form contains magnesium and other minerals, including asbestos.

The tests were made as part of the FDA's ongoing investigation after reports in 2017 that some cosmetics sold by Claire's contained tremolite asbestos. The agency released a call to action that cosmetics manufacturers should register their products in the Voluntary Cosmetic Registration Program (VCRP).

The latest recall comes three months after Claire's pulled three products- compact powder, contour powder and eye shadows from its stores in March 2019 due to their contamination. However, at that time, Claire's disputed FDA's findings and said that the products were safe, and the decision to recall them was "out of an abundance of caution."

The FDA also encouraged healthcare professionals and consumers in their June 6 notice to report to its MedWatch Adverse Event Reporting program any "adverse events" caused by using the products.

Claire's said it "will provide a full refund to any customers who purchased the JoJo Siwa Makeup Set.

EPA Releases Proposed Interim Registration Review Decision (PID) for Glyphosate acid and its Salts

By LisaLisa | States Pass New Chemical Laws and Regulations

The U.S. Environmental Protection Agency (EPA) has announced it has released its Proposed Interim Registration Review Decision (PID) for glyphosate acid and its various salt forms. 84 Fed. Reg. 19782. In the PID, EPA states that it "did not identify any human health risks from exposure to any use of glyphosate" but did identify "potential risk to mammals and birds" within the application area or areas near the application area and "potential risk to terrestrial and aquatic plants from off-site spray drift, consistent with glyphosate's use as a herbicide." Even with these potential risks, the PID states that "EPA concludes that the benefits outweigh the potential ecological risks when glyphosate is used according to label directions" and proposes certain risk mitigation strategies, including:

- "To reduce off-site spray drift to non-target organisms, the EPA is proposing certain spray drift management measures" with specific spray drift mitigation language to be included on all glyphosate product labels for products applied by liquid spray application;
- "To preserve glyphosate as a viable tool for growers and combat weed resistance, the EPA is … proposing that herbicide resistance management language be added to all glyphosate labels" and to require measures "for the pesticide registrants to provide growers and users with detailed information and recommendations to slow the development and spread of herbicide-resistant weeds";
- Inclusion on labels of a non-target organism advisory statement to alert users of potential impact to non-target organisms; and
- "EPA is also proposing certain labeling clean-up/consistency efforts to bring all glyphosate labels up to modern standards."

EPA states that these measures were discussed with glyphosate registrants, who do not oppose the proposed risk mitigation measures outlined in the PID.

The public can submit comments on EPA's proposed decision at www.regulations.gov in Docket Number EPA-HQ-OPP-2009-0361. Public comments are due by **July 5, 2019**. In addition to the PID, EPA is also posting to the glyphosate docket EPA's response to comments on glyphosate's usage and benefits (dated April 18, 2019), EPA's response to comments on the human health risk assessment (dated April 23, 2018), and EPA's response to comments on the preliminary ecological risk assessment (dated November 21, 2018).

This PID was issued shortly after the Agency for Toxic Substances and Disease Registry's announcement on April 8, 2019, of the opening of a docket on the draft toxicological profile for glyphosate. 84 Fed. Reg. 13922. ATSDR seeks comments and additional information or reports on studies about the health effects of glyphosate for review and potential inclusion in the profile. Comments are due by **July 8, 2019**.

EPA's PID and related documents, along with ATSDR's draft profile and the peer review which will follow, can be expected to become part of the larger debate about the potential risks of glyphosate. In 2017, EPA evaluated the carcinogenic risk of glyphosate and released it's draft human health and ecological risk assessments.

EPA's PID is interesting not only for the conclusions EPA reached following its review of data submitted by registrants in response to a data call-in (DCI) and following the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel's (SAP) meeting to consider and review scientific issues related to EPA's evaluation of the carcinogenic potential of glyphosate, but for the issues that remain to be addressed. Notably, EPA states that it has not considered the petition filed on September 27, 2018, to reduce glyphosate's tolerance because the petition was filed after the comment period for the human health and ecological risk assessments closed. Instead, EPA plans to post the petition in the glyphosate docket and address the petition concurrently with the development of the Interim Registration Review Decision.

In addition, EPA has not in the PID or related documents addressed issues regarding it's Endangered Species Act (ESA) assessment or it's Endocrine Disruptor Screening Program (EDSP) activities. EPA states it intends to complete an assessment of risk to ESA-listed species prior to completing its final registration review decision for glyphosate, and that it also will make an EDSP determination under Federal Food, Drug, and Cosmetic Act (FFDCA) Section 408(p) before completing its registration review. EPA also notes that it continues to evaluate risks to pollinators and that if it determines "that additional pollinator exposure and effects data are necessary to help make a final registration review decision for glyphosate, then the EPA will issue a DCI to obtain these data." Although there are significant areas that remain to be resolved, EPA issued the PID "so that it can (1) move forward with aspects of the registration review case that are complete and (2) implement interim risk mitigation."