

PRODUCT SAFETY:

CALIFORNIA PROPOSITION 65

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PROPOSITION 65 BACKGROUND

In a voter referendum in November 1988, an initiative named Proposition 65, a/k/a California Clean Air and Water Act, was passed by the voters. The concern at the time was with carcinogens in the water and in the air. The wording in the Act requires that "no person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the State to cause cancer or reproductive toxicity without first giving clear and reasonable warning." When the initiative came up, there was no overt connection made with products being sold at retail or in our industry, but with the passage of time, the Act has evolved significantly.

It is important to understand the process that brought the Act about. First off, it is not a product of legislation, so the state is effectively unable to do much about it, either by definition of the level of hazard, the enforcement of the provisions of the Act, or any exemptions from the Act. The state legislature cannot even amend the Act, since it was not their product to begin with.

There are now over 800 chemicals that have been identified as being "known to the State of California" as being carcinogens or causing birth defects.

Proposition 65 may be enforced by the California Attorney General, public enforcers such as district attorneys, and private plaintiffs suing in the public interest (after they have first served a 60-day notice of violation on all public prosecutors and no public prosecutor proceeds to enforce the alleged violation. A plaintiff may seek injunctive relief as well as penalties of \$2,500 per violation per day. A more general California statute allows most successful plaintiffs to recover their attorneys' fees as well.

It is important to note the very long reach of Proposition 65 liability. One need not be doing business in California to be in the chain of Proposition 65 litigation. Indeed, you could be a New Jersey distributor of products sold to you by a Massachusetts supplier, and your client could be doing business in New York, with no California affiliation. Should one of the items you sold to your client end up in California, you and your supplier and your client could be named as defendants in a Proposition 65 lawsuit, and the venue would be in California.

PLAINTIFF'S BURDEN OF PROOF

The plaintiff under Proposition 65 has the burden of showing that a business caused exposures to a listed chemical without a warning. To meet this burden of proof, the plaintiff does not need to show that he/she or any member of the public actually suffered any actual harm from these exposures, and does not need to show that the exposures exceeded any particular levels or standards.

To bring a lawsuit, a plaintiff must first issue a sixty-day notice letter and serve it on the alleged violator, the California Attorney General, or a California district attorney. In issuing this notice, a plaintiff must provide a "certificate of merit." The certificate of merit must state that the person executing the certificate has consulted with experts who reviewed the data regarding the exposures at issue and that, based on that information, there is a reasonable basis for a private action.

A Proposition 65 plaintiff must also show that a business "knowingly and intentionally" caused exposures to a listed chemical without a warning. By the way, "knowingly" refers only to knowledge of the fact that exposure to a listed chemical is occurring. No knowledge that the exposure is unlawful is required. However, if someone in the course of doing business, through misfortune or accident and without "evil design, intention or negligence," does something which results in exposure, then he/she has not violated the Act.

There are no published cases that will help define the term "knowingly." Even if a defendant claims that it did not have actual knowledge that its product contained a listed chemical, plaintiffs frequently take the view that a company has knowledge when it "should have known" of the exposures. This is particularly the case when other companies in the same industry have been sued for similar claims under Proposition 65, as is the case regarding claims of lead exposures in the promotional products industry. In a nutshell, ignorance is no defense in Proposition 65 litigation.

The term "intentionally" is also not defined in the regulations, or in any of the published cases. The Attorney General has said that the term means "to act in a purposeful manner, with deliberateness and design." A plaintiff does not need to prove that someone specifically intended to cause exposures to a listed chemical, only that it intentionally manufactured, distributed, or sold the product at issue, which contained the listed chemical. In other words, you cannot claim that you didn't know that the bag or bottle had lead in the ink, and exempt yourself from liability. If you sold the item, you are in the chain of litigation.

DEFENDANT'S BURDEN OF PROOF

If a Proposition 65 plaintiff meets its burden of proof, a defendant has to prove an affirmative defense to the action in order to avoid liability. One defense is to show that the exposures at issue will have "no observable effect assuming exposure at 1,000 times the level in question" for reproductive toxicants such as lead. This level, often referred to as the "maximum allowable daily dose level" ("MADDL" for short), is extremely conservative. It incorporates a 1,000-fold safety factor over and above the level at which reproductive effects are observed. If a defendant can show that exposures to a reproductive toxicant do NOT exceed the MADDL, then a warning is not required for those exposures.

For listed carcinogens, if a defendant can show that exposures to a product do not exceed the "no significant risk level" ("NSRL"), then a warning is not required for those exposures. The NSRL is the level that is calculated to result in not more than one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime.

There have been hundreds of Proposition 65 cases brought since 2002 regarding inks and paints on the exterior decorations of glassware and ceramicware. The chemicals at issue in these cases have been lead and, to a lesser extent, cadmium. As a result, any evaluation of inks from the standpoint of Proposition 65 should be focused on lead and cadmium in particular.

The state agency handling lead for Proposition 65, the Office of Environmental Health Hazard Assessment (www.oehha.ca.gov), has established MADDLs and NSRLs for a handful of listed chemicals. For chemicals that do not have published or established acceptable levels, the burden is on the defendant to establish an appropriate MADDL or NSRL, and to show that the exposures in its products do not exceed these levels. To prove this defense requires preparation of a risk assessment, and is quite complicated...and open to challenge by the plaintiff.

The safe harbor MADDL for lead is 0.5 micrograms (one half of one millionth of one gram) per day, and 4.1 micrograms (4.1 millionths of one gram) for cadmium. So, if a defendant can prove that its product does not cause exposures exceeding these levels for lead and cadmium, then it is not required to provide Proposition 65 warnings for those exposures.

For exposures to consumer products, such as promotional items, the level of exposure to the listed chemical is calculated using the "reasonably anticipated rate of intake or exposure for average users of the consumer product." In the case of inks that do not come into direct contact with food, the exposures would likely only be indirect. In other words, lead and cadmium in the inks may transfer to a person's hands, and then some amount of that lead may be ingested when the person handles and eats food, for example.

Gold colored lead paint on the rim of a decorated ceramic mug, though, would be considered to have direct contact with food.

Determining what the permissible content-based level of lead (or any other Proposition 65 listed chemical) is for inks under circumstances involving indirect exposures is not readily apparent from the regulations. Proposition 65 settlement agreements, which technically only apply to the settling parties, have been quite useful to other companies in estimating allowable content-based limits of listed chemicals in the products. The settlement agreements in many cases seem to have clustered around similar agreed acceptable levels of the listed chemical in question, and thus are providing a sort of common law set of standards based on litigation results.

ANALYSIS

Most of the settlement agreements involving glassware and ceramicware with exterior decoration have specified content-based limits for lead and cadmium as follows:

Lead: no more than 0.06% (600 parts per million "ppm" of the decorating material may contain lead.

Cadmium: no more than 0.48% (4800 ppm) of the decorating material may contain cadmium.

For children's products, however, the limits established by settlement agreements are lower:

Lead: no more than 0.02% (200 ppm) of the decorating material may contain lead.

Cadmium: no more than 0.08% (800 ppm) of the decorating material may contain cadmium.

For the "lip and rim" area of decorated glassware and ceramicware (where the lead or cadmium in the decoration may be directly ingested), the decoration must meet the same standards required for children's products above.

INKS

Several ink vendors used by supplier companies in this industry, have provided "Statements of Compliance" regarding chemical constituents of their inks. These Statements indicate that lead is generally present at less than 25 ppm and cadmium is less than 25 ppm in the inks. These levels are well below those established in the Proposition 65 settlement agreements shown above.

Other Proposition 65-listed chemicals identified in the Statements of Compliance are antimony, arsenic, selenium, mercury, and chromium. These chemicals are also present at very low levels: less than 50 ppm, 25 ppm, 100 ppm, 25 ppm, and 25 ppm, respectively. Although it is possible, it seems unlikely that the levels of these chemicals, which have NOT been at issue in any of the hundreds of Proposition 65 lawsuits regarding decorated ceramicware and glassware, would give rise to a Proposition 65 enforcement action brought by a private plaintiff.

For inks, a private Proposition 65 plaintiff is likely to focus on lead and, to a lesser extent, cadmium. Plaintiffs often do initial testing for lead by using "wipe tests," which are easily available and relatively simple to use. If the lead levels are below 200 ppm, a typical plaintiff would likely be discouraged from bringing a lawsuit unless other factors are involved, such as an advertisement that the product is "lead free," or other doubtful claim.

CASE HISTORIES:

MELAMINE IN PET FOOD AND MILK

POWDER

MATTEL

ADIDAS

DENTAL IMPLANTS

PROMOTIONAL PRODUCT
DISTRIBUTORS

MELAMINE

Product Safety first made headlines in 2007 with pet food contaminated by melamine, an industrial chemical that mimics protein. Ingredients for pet food originating in China, used by several dozen brands of product, quickly found their way into the pet food supply chain and ended up killing thousands of American dogs and cats.

There were recalls of pet food across the country, as marketers attempted to limit the damage.

The head of China's equivalent of the FDA was executed for his agency's failure to prevent this incident.

About a year later, there was international concern about melamine in powdered milk, often used as the base in infant formula. In China alone, 53,000 children became ill as a result, and at least four died. A few months later, Cadbury Chocolates® had to recall ten different candies made in its plant in Beijing, when it was discovered that milk tainted with melamine was being used in production. Two brothers involved in selling the contaminated milk could face death if convicted. The raw milk had been watered down, and melamine was added to make it appear normal. Ingesting melamine can lead to kidney stones, urinary tract ulcers, and eye and skin irritation. It also robs infants of needed nutrition.

MATTEL

In the fall of 2007, Mattel initiated several recalls of its toys due to contamination of lead in the paint. Recalls amounting to over 22 million units involved the following brands:

Fisher-Price Toys, including 90 toy products

Pixar Cars: eight toy products

It's a Big Big World ™: one product

Geo Trax ™: two products

Barbie ® Accessory Sets: seven products

Go Diego Go! ™: one product

COSTUME JEWELRY

Adidas imported 200,000 sets of costume jewelry as a premium for its athletic wear, but found that the product contained unacceptably high levels of lead, under California's Prop 65.

The company ended up recalling the whole lot, and discontinued the promotion. No legal action was taken against Adidas.

DENTAL IMPLANTS

Early this year, a woman on Long Island, who had just had a dental implant performed, was experiencing severe headaches and dizziness. She went back to the oral surgeon and learned that the implant had been made in China and was made of lead. The news article went on to say that the dentist had charged his patient \$3,000 for the procedure, but had paid his overseas supplier just \$17 for the implant. The patient is suing the dentist for a large amount of money.

In Europe, instead of using a surgically-implanted post to hold a replacement tooth, a common practice is to use a less invasive technique. These non-invasive implants contain high amounts of arsenic.

PROMOTIONAL PRODUCTS DISTRIBUTORS

In 2006, a major distributor in the promotional products industry, was sued privately for alleged violation of Proposition 65. While the facts of the case are not publicly available, the parties agreed to settle after the defendant had spent over \$35,000 in legal fees, with no end in sight. The profile of the plaintiff was that he had made a practice of suing companies under Proposition 65 with the expectation that they would agree to settle before the cases got to court for trial. The cost to bring a case is modest, and requires little effort or risk.

A year or so later, a small distributor in the Bay Area took an order from the State of California for over 50,000 backpacks, and placed the order with an importer in Southern California. The state had the products tested for lead, and found the inks had an unacceptably high level of contamination. The state rejected the backpacks and returned them to the distributor. Although the importer claimed to have tested the product for Proposition 65 compliance, he would not agree to take them back. As a result, both the distributor and the importer went out of business.

RECOMMENDED PRACTICES TO
PROTECT YOUR CLIENTS AND
YOUR OWN BUSINESS

RECOMMENDED PRACTICES

Given the treacherous landscape for promotional products suppliers and distributors, what are some of the things we can do to protect our businesses and our clients?

First off, can we get insurance?

No insurance company we are aware of will write protection against lead contamination, which is the most common element involved in Proposition 65 litigation. That should tell us something about the risks involved.

Second, how about getting an indemnity agreement from the supplier?

Generally, suppliers are loath to write such agreements, and will only do so with carefully

worded legal caveats that effectively limit their liability.

Third, what about testing the products for Proposition 65?

For domestically manufactured products, this is something your supplier should do and have documentation for. American manufacturers have a major advantage in product safety, since their materials suppliers generally have to provide Material Safety Data Sheets and meet Agreed Quality Levels. If an American materials supplier changes ingredients without informing its customer, such an action could constitute civil fraud under the statutes.

For importers, the situation is far more complex. Should you test randomly the products in the container, or test every one of them? If you are satisfied that one container has acceptable product, should you test the others in the same shipment? What if you were satisfied with the products in the initial delivery? Should you assume the next shipments will be identical in the quality of materials?

Still, most importers custom-decorate their product to suit the needs of our industry, and most of that work is done in the United States. In those cases, the source of the inks and other materials used is of central interest. Again, you should be able to obtain MSDS sheets and a Statement of Compliance with Proposition 65 from the ink supplier.

EDUCATE YOUR CLIENTS

In the present environment, product safety is becoming ever more important to our end buyers and clients. For example, take the case of a high-end hotel chain that enjoys high recognition due to years and years of successful performance, client satisfaction, and a series of well thought-out promotions to underscore their positive message. Would it not make sense for this client to re-evaluate the use of promotional products due to concerns about product safety?

What if the arrival gift is contaminated with high levels of ink in the custom decoration?

What if the cookies in the custom-decorated tin have melamine in them?

What if their glassware is decorated with gold-colored lead ink on the rim?

Now, imagine that the marketing director for this hotel chain is concerned about the risk/reward of using promotional products. He/she has read about promotions that went wrong due to product safety defects, and is concerned that the use of promotional products may jeopardize the firm's good reputation. In this instance, it may be best to demonstrate that you are knowledgeable about product safety, that you understand the concern about harming their "brand equity," and that you can help them avoid this kind of hazard in their next promotion.

Isn't this knowledge and awareness of the issues surrounding product safety concerns, a true value-added that you can bring to the client?

Compare that approach with that of the previous promotional products sales rep: "Here's a great idea!! It's really colorful, will make a great impression, and won't cost you an arm and a leg. The lead time is just a few weeks, and I can get you a great price on it."

In the present environment, smart buyers want more value-added from their promotional products consultant. They don't want a peddler; they want a professional who can help them to market successfully and protect their brand equity at the same time.

OUTLOOK FOR PRODUCT SAFETY:

ENHANCED REGULATION

TIGHTER STANDARDS

TRADE RESTRICTIONS

ENHANCED REGULATION

The recent shift in the political landscape, along with widespread concerns about consumer protection, are leading inexorably toward a higher level of product safety regulation. California's Proposition 65, for all of its faults, was for years, the most visible effort to attempt to tighten product safety standards to protect the consumer. Until recently, only very limited action was taken at the Federal level. We had the Consumer Protection Agency, but that was largely concerned with product design issues, not the materials used in their manufacture. And we had the Food and Drug Administration, whose efforts involved the safety of the nation's food supply and the regulation of the medical devices and pharmaceuticals industries. And we had the Federal Trade Commission, which was concerned with fair trade practices and product claims.

The notion that products could be unsafe due to the materials used in their manufacture was not high on anyone's list of concerns until we began to see the series of stories of contaminated product coming out of China in the past few years. Now, with companies like Mattel and Cadbury being taken unawares, an enhanced level of attention to product safety has taken hold in the country at large.

The next wave of regulation began with the Consumer Product Safety Improvement Act of 2008 (CPSIA), or HR # 4040. In response to the widespread concerns about children's toys being contaminated with lead paint, the Congress passed the Act last summer. Although temporarily delayed due to pushback from the toy industry, the CPSIA calls for products that are intended for use by children 12 and under to meet certain tests. For example, products made prior to December 12, 2008, must be certified to be below 600 ppm lead (the Proposition 65 standard for children is 200 ppm). By August 2009, the lead count is to fall to not more than 300 ppm, with a goal of 100 ppm by 2011 (or substituted amount based on feasibility).

In addition, phthalates, which are used commonly to plasticize materials like PVC to make them more pliable and to extend their useful lives, are prohibited under the Act in children's products above a minimal level due to concerns about their possible disruption of the normal workings of the endocrine/hormonal system. The science is far from fully developed in this regard, and industry claims the materials are safe, but the political process moved in anticipation that there may be something to the public's concerns.

It is nearly certain that more legislation like CPSIA will be forthcoming, both at the Federal and at the state level.

TIGHTER STANDARDS

With the shift in political winds across the country in the past couple of years, it is inevitable, and desirable in many cases, that product standards be made tighter, in order to protect the consuming public. This is a long-standing tradition in America, most visibly represented by Ralph Nader's successful campaign for auto safety a generation ago.

We can expect more stringent standards for product design, to reduce or prohibit the small magnets in toys that are known to endanger young children. And we can also anticipate that we will have fewer materials options, as well. It was not long ago, for instance, that lead paint was preferred because it had better color properties, and lasted longer than other paints.

The hope is that new legislation will spell out the "safe harbor" standards that we are to meet. The greatest flaw in Proposition 65 is that there are no set standards, and the so-called "safe harbors" are actually the result of litigation settlements, a very expensive and inefficient process.

TRADE RESTRICTIONS

With the problems the Chinese have created for themselves with inconsistent product quality and the use of inappropriate materials, it is a good bet that the United States will impose trade restrictions with the apparent goal of protecting the American consumer. In addition to this worthy goal, such restrictions would have the affect of reducing our trade imbalance with China, at least until they can get their house in order.

Such trade restrictions would artificially re-level the playing field and enable those suppliers who can deliver "safe" product to gain back market share, in some cases, other developing countries with better regulatory capabilities will benefit, and in others, North American and European manufacturers will find they are once again able to compete with low wage countries.

In time, should such trade restrictions be put in place, China will have to respond internally and find ways to produce products that meet the new standards. In the long run, this should work to the advantage of all parties in global trade. The question is, will our government have the political will to put such needed elements in place?

WHAT SHOULD OUR INDUSTRY DO
ABOUT PRODUCT SAFETY?

BE POLITICALLY ACTIVE

QUANTIFY STANDARDS FOR
PRODUCT SAFETY

CERTIFICATION

BE POLITICALLY ACTIVE

With the spate of new laws regulating product designs, materials, and marketing practices, our trade associations (PPAI and our regionals) have to be more and more politically active. PPAI has developed a relationship with the toy manufacturers trade association, due to common interests in Proposition 65 and the CPSIA.

We can expect the politicians to favor more restrictive regulations regarding product safety, at both the Federal and state levels. These anticipated safety guidelines will make it ever more difficult for our industry to use imported items until China and other cheap labor sources can adapt to the new landscape.

Regarding marketing issues, there is a bill in Congress now that would prohibit pharmaceutical firms and other suppliers to the health care industry from giving promotional items to health care practitioners (Pete Stark, D-CA). Similar bills are being offered in several state legislatures.

QUANTIFY STANDARDS FOR PRODUCT SAFETY

With the increasing attention being paid to product safety, it seems clear that our industry trade association should take a leadership role in quantifying product safety standards for suppliers and distributors to follow in order to meet compliance requirements in the various jurisdictions.

There are testing laboratories that can provide this information to PPAI at little or no cost, so it can be shared with the membership. This would reduce the time needed, and eliminate the cost, for individual members to pull the information together. As we have seen earlier, the standards for lead are not the same for Proposition 65 and CPSIA. As new standards come into play, it would be most helpful to the members of PPAI to have a single source that can readily share the requirements under the various statutes and regulations.

CERTIFICATION

PPAI could take an important step for all members by providing a certification program for products that meet the standards for product safety. The model for this is the Good Housekeeping Seal of Approval, which has been in existence since 1909. Good Housekeeping is widely recognized as the most respected source of information about products for the home, and its seal is of great value to the magazine's readers and its advertisers.

Our association could establish some simple guidelines for its own version of the Seal of Approval, and promulgate them to its members. Elements to consider would include the levels allowed of lead, cadmium, arsenic, and other potentially hazardous materials in promotional products. The standards for earning the Seal of Approval would be the most stringent of the legislated safe harbors then in effect.

The supplier would be responsible for obtaining laboratory test results that demonstrate compliance, and PPAI should designate those laboratories that it considers acceptable for this purpose. PPAI need not take on any liability for this program, since it would be the testimony of the supplier that will determine whether the Seal of Approval is merited or not.

Such a system would be voluntary for PPAI supplier members, and would give distributors an important attribute to recommend to their end buyers.

CONCLUSION

Proposition 65 was the opening salvo in what appears to be a continuing string of regulations governing product safety. California voters approved the initiative over 20 years ago in an effort to make sure drinking water and air quality did not present undue risk of cancer or birth defects. In the intervening years, this measure has greatly extended its reach, and now over 800 specific chemicals are listed as "being known to the State of California" to be carcinogens or cause birth defects.

Because Proposition 65 was not a product of the state legislature, that body cannot set "safe harbor" limits on the chemicals specified, and the rules are effectively not capable of being amended without another state-wide vote. Safe harbor levels for lead and cadmium specified in this paper are the result of hundreds of litigation settlement agreements, which tended to cluster around a narrow band of accepted outcomes. This is a terribly costly and inefficient way to develop public policy, but is inherent in the way the legislation got on the books.

We should be encouraged that the Congress got into the fray last year with CPSIA. Because Congress passed a law, the legislation can be amended to keep it up to date with current practice as that evolves in the years ahead. Also, having Federal standards is far preferable to having a state by state patchwork of regulations and standards.

Product safety concerns will only become sharper in the next few years, and our industry cannot ignore this trend or simply hope it will go away. It won't. Rather, our industry has an unusual opportunity to cooperate with this wave, rather than fight it, and to raise our standards of practice to make product safety a major benefit to the end buyer, from working with professional promotional products distributors and suppliers.