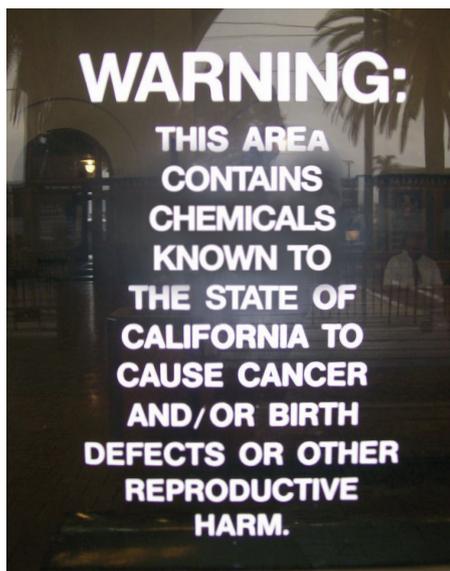


California Proposition 65

by John Hubbard



Reviewing the stringent chemical legislation for products on sale in the state of California.

'Proposition 65' is also known as the 'Safe Drinking Water and Toxic Enforcement Act'. Published in 1986, it is intended to improve consumer health protection by requiring suppliers of articles to label any products containing chemicals identified as being carcinogenic or having an adverse effect on development or reproductive health.

A requirement of the legislation is that, at least once a year, the list of chemicals known to cause cancer or have reproductive toxicity is updated by the office of the Governor of California. At the time of writing, the current list encompasses in excess of 700 substances. Small businesses (those with less than ten employees), governmental agencies and public water systems are exempt from the requirements of Proposition 65.

Proposition 65 warnings

The statute requires that 'no person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known, to the state (California), to cause cancer or reproductive toxicity without first giving a clear and reasonable warning...'. This means that if products supplied to the public are known to contain any of the chemicals included in the Proposition 65 list at a level that could be judged to pose a risk to the user, the product should be labeled with a clear warning at the point of sale.

In order to determine if the level of the Proposition 65 chemical is sufficiently high to pose a risk to the user, the Californian Office of Environmental Health Hazard Assessment (OEHHA) publishes the 'safe harbor' levels for some (but not all) of the chemicals listed. The safe harbor levels are exposure levels quantified in microgrammes per day ($\mu\text{g}/\text{day}$). These are expressed as 'No Significant Risk Levels' (NSRLs) for carcinogenic chemicals and 'Maximum Allowable Dose Levels' (MADLs) for substances that cause reproductive toxicity.

Where safe harbor numbers do not exist for any chemicals on the Proposition 65 list, the supplier of products containing these substances should make a decision based on a risk assessment, taking into account the concentration of the chemical, published toxicity data and the potential exposure routes for the user.

The list of the Proposition 65 chemicals should not be seen as a ban on the specific chemical. It should, rather, be viewed as a requirement to ensure that users are informed about the potential risks involved and are able to make decisions based on that information.

Testing for Proposition 65 chemicals

There is no mandatory requirement to carry out testing as part of the risk assessment within Proposition 65. However, testing may become necessary where detailed information on the chemicals used in the formulation of the product may not be available. Testing should be based on known product composition and processing

techniques; it is clearly not practical to analyze the full range of materials that may be present in a single consumer product item for all of the Proposition 65 chemicals.

Communication is, therefore, an important element within the California Proposition 65 legislation. Suppliers need to provide concise information about the formulation and also the use of any chemicals used in the manufacturing process. This will apply to all products – whether they are manufactured in the U.S.A. or elsewhere.

Specific concerns have been expressed about the use of phthalate plasticizers in flexible PVC materials and the use of lead and cadmium pigments, particularly in tableware glazes. However, the new requirements for lead in the Consumer Product Safety Improvement Act (CPSIA), which is federal legislation (that is, law across the U.S.A.), will take precedence over Californian state law. Therefore, where the requirements are more stringent, the federal law will apply.

In summary

The California Proposition 65 requires companies to ensure that there is information available at point of sale to warn consumers of carcinogens and chemicals that are toxic to reproduction, so that informed decisions can be taken. Organizations should ensure that their supply chain is familiar with the current lists, and to highlight if these chemicals are used. As mentioned earlier, the legislation is not an actual ban on the chemicals listed. It is a mechanism to reduce exposure and, thereby, reduce risk of ill health.

How can SATRA help?

SATRA is able to offer guidance, consultancy, training and testing on all aspects of chemical legislation. Our chemical laboratory is an accredited third-party test house for CPSIA lead testing. For further information, please email james.corton@satratechnology.com