

Testing for Compliance

If you sell into the European market, then chances are you know the terms REACH and RoHS. REACH is a European Regulation on **R**egistration, **E**valuation, **A**uthorization, and restriction of **C**hemicals. It went into effect in 2007 and has been expanded upon each year since. REACH works with the European Chemicals Agency (ECSHA) on the determination and implementation of regulations. Chemical imports into the EU must be registered within the REACH program. One portion of REACH is the Substances of Very High Concern (SVHC) list. This list contains materials of concern due to environmental health and safety risk factors. The substances are restricted both in pure chemical form and within a product or article. REACH requires chemicals and chemical components being produced or imported to the EU to be registered. Depending on the type of chemical, there can be various requirements for reporting.

RoHS (Restriction of Hazardous Substances) is also a compliancy regulation within the European Union. It originated as Directive 2002/95/EC and focused primarily on the electrical and electronics industry. RoHS has a more focused target. They regulate the limits of ten restricted substances.

1. Cadmium (Cd): < 100 ppm
2. Lead (Pb): < 1000 ppm
3. Mercury (Hg): < 1000 ppm
4. Hexavalent Chromium: (Cr VI) < 1000 ppm
5. Polybrominated Biphenyls (PBB): < 1000 ppm
6. Polybrominated Diphenyl Ethers (PBDE): < 1000 ppm
7. Bis(2-Ethylhexyl) phthalate (DEHP): < 1000 ppm
8. Benzyl butyl phthalate (BBP): < 1000 ppm
9. Dibutyl phthalate (DBP): < 1000 ppm
10. Diisobutyl phthalate (DIBP): < 1000 ppm

Failure to fall within the limits of these substances can prevent companies from selling their product within the EU.

California Proposition 65, originally known as the Safe Drinking Water and Toxic Enforcement Act of 1986, is a state law that was passed by voter ballot in November 1986. The law was formed to help protect drinking water from substances that cause cancer, birth defects, or other chemical harm. The law is managed by the California Office of Environmental Health Hazard Assessments (OEHHA). The Proposition 65 List is an official list of all restricted substances and required limits. Currently the law does not restrict the sell of products that fail to meet the requirements, only requiring them to be accompanied by a letter stating that they do not comply to the Proposition 65 requirements. Additional labeling and notifications are often required. OEHHA regularly updates the materials and limitation thresholds on the Proposition 65 List. The most up to date list can always be found on their [website](#).

Determining if you comply with these regulations requires testing products and obtaining quantitative values for regulated elements, typically done by an accredited independent laboratory. These laboratories will use various analytical equipment to perform the analysis.

ICP (inductively couple plasma) is the most common method for analysis for metallic substances. Prior to analysis, the ICP samples need to be digested into a solution. This can be done in a hot block using concentrated acid or by using a microwave digestion unit.

The ICP decomposes the sample into constituent elements and then into ions. Those ions are then analyzed by spectroscopy.

ICP analysis can detect trace level amounts of hazardous heavy metals such as lead (Pb), Cadmium (Cd), Beryllium (Be) and chromium (Cr+6). Detection of mercury compounds is another common analysis. ICP can also analyze for residual catalyst such as tin or platinum.

An XRF (X-Ray Fluorescence) can be used for some levels of elemental detection. Depending on the unit, detection may not reach trace level. Analysis by XRF is a non-destructive method and typically does not require any sample preparation. The XRF works by emitting an x-ray beam strong enough to affect the atom shells within the sample. The beam displaces the electrons from the orbital shell. This causes the electrons from the next shell up to displace it. When this occurs, there is an energy loss. The amount of energy loss between the two electrons is used to identify the element. Individual proportions of energies are calculated to determine the quantitative value.

Gas chromatography (GC) can be used to detect non-metallic substances of concern which includes phthalates, nitrosamines, siloxanes and phenyls. Like ICP analysis, samples have to be prepared before testing. Instead of digesting samples like you do for ICP, you extract samples for gas chromatography analysis. Methylene chloride is often used to perform these extractions. For best quality results accelerated solvent extraction (ASE) equipment should be used.

In gas chromatography there is a gas separation phase that carries the sample molecules through the columns for analysis. This is done using an inert gas such as helium. The sample passes through solid (liquid) phase analysis followed by a vapor (gas) phase analysis.

Mass spectrometry (MS) is often coupled with other analytical equipment such as an ICP (ICP-MS) or a GC (GC-MS). MS analysis uses electric and magnetic fields to measure the mass of the ions.

Not all environmental testing is related to a regulatory standard. There is industry related and application specific standards as well. An example would be the evaluation of leachable contaminants for drinking water related gaskets and seals. Medical applications have stringent requirements on many of the same substances listed in regulatory compliances. Limits for these substances are often much smaller. This requires a greater detection capability for the test equipment.

It is important to select a laboratory that has a strong understanding of the regulatory standards, reporting levels, and testing methods. A skilled analytical chemist will be needed to analyze the data and interpret the results. Equipment that has the proper detection levels and calibrations is critical to gaining accurate data.

As global initiatives grow for environmental awareness, compliancy regulations will expand. The REACH list continues to grow every year. California Proposition 65 will likely expand over time, going from a

notification requirement to restrictions. It is likely that other states will begin to adopt these regulations as well. As long-term effects of substances become more discovered, limits and regulatory controls will be adjusted. Environmental and compliancy regulations are not going away. Design, develop, and formulate your products with future expanded regulations in mind. Products meeting the minimum level of requirements today will soon fall out of compliancy as regulations grow. Innovation is being driven by these growing regulations. Phthalate free plasticizers, nitrosamine free accelerators, and low metallic activators are the wave of the future for our industry.

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