Understanding RoHS and REACH: Impacts on your Global Markets

An overview of two important environmental regulations, their impacts on the global electronics industry.

Abstract

Companies manufacturing equipment or consumer parts that use hazardous materials in the manufacturing process must comply with environmental regulations from multiple geographic markets. Two key sets of regulations – RoHS2 and REACH – require compliance if you are selling to markets in the European Union, China, Korea, and parts of the United States. The list of markets with materials controls related to electronics changes periodically. Compliance with RoHS2 and REACH requires extensive knowledge of your supply chain, excellent record keeping, and in some cases testing. Whether you are an OEM or a supplier, understanding the restrictions on hazardous materials and compliance is critical to maintaining and expanding market share. This white paper provides a description of the basic RoHS2 and REACH requirements, enforcement and compliance.
Global markets require awareness and understanding of hundreds of requirements from packaging and transportation to import and export regulations. For electronics original equipment manufacturers (OEMs) and suppliers, there are added environmental requirements. These regulations require OEMs, and by extension their suppliers, to document the materials that the equipment and parts are made of and come in contact with during the manufacturing phase.

RoHS – The Basics

Since July 2006, electronics companies with markets in the European Union (EU) have been working with the materials restrictions enforced under the Restriction of Hazardous Substances (RoHS) directive. RoHS regulations are applicable around the world – in one form or another. Countries outside the EU either have slightly different restrictions or may treat classes of products differently. Countries within the EU may handle implementation of RoHS differently as well.

Compliance with the EU’s RoHS directive requires that manufacturers track the amounts of each restricted substance in their end products, keep records, and report as required by government agencies.

For OEMs using hundreds or thousands of parts from multiple suppliers, the task of identifying and keeping track of all the materials used in their products and the amount of each material to demonstrate compliance is one of the most difficult tasks. Finding a quality, comprehensive source for materials information can make or break a company’s effort to comply with RoHS.

RoHS Transitioning to RoHS2

In 2013, RoHS transitioned into the RoHS Recast or the RoHS 2 Directive. Legislators and manufacturers found some legal requirements and exemptions of RoHS lacked clarity. Ambiguous language made it difficult for manufacturers to comply with the directive and for legislators to enforce it. RoHS2 aimed to add legal clarity to the directive while expanding its scope.

RoHS required compliance from 8 different product categories. RohHS 2 expands that list to 11 categories. The new product categories introduced in 2014 are medical devices and monitoring and control instruments. In 2019, all other electrical equipment (EEE) not covered by other categories, unless specifically excluded.
RoHS2 carries a new CE Marking Directive, which requires all EEE products to visibly, legibly, and indelibly affix a CE mark to the finished product or its data plate. This directive went into effect in 2013. As a part of the process of obtaining the CE Mark, manufacturers must draw up a Declaration of Conformity (DoC) before a product can be placed on the market. The DoC must contain technical documentation that clearly demonstrates compliance with RoHS2 standards. The marking directive is considered to be a vital component to the enforceability of RoHS2- for the first time, it will be easy for anyone to immediately identify whether or not a product is compliant.

For now, the same substance restrictions of RoHS apply for RoHS2 in Europe. As with RoHS, substance restrictions are as follows (See Figure A), though many product exemptions may apply.

REACH Legislation

On June 1, 2007, the EU and member states of the European Economic Area imposed new regulations for the Registration, Evaluation, Authorization, and Restriction of Chemical substances, commonly referred to as REACH. With a goal of better protecting human health as well as the environment, REACH is the strictest law to date regulating chemicals and their safe use, and replaced over 40 existing directives related to chemical management under one regulation. Any company that manufactures, imports, or distributes products in Europe, must comply with REACH legislation.

Difference between REACH and RoHS2

REACH is much broader in scope than RoHS2. While RoHS2 covers only six hazardous materials and focuses on those used in the
manufacturing of electronics, REACH will target and control the use of thousands of substances and is not limited to the electronics industry. For instance, cars, toys, furniture and even clothing can be subject to REACH provisions. Chemicals subject to the legislation include substances on their own; those used as intermediates; those used in the making of a product, such as inks, alloys, solvents and paints; and those used in the final product itself where the substance may be released during normal consumer use.

The REACH Process

The REACH process is overseen and managed by the European Chemicals Agency (ECHA) in Helsinki, Finland. The agency is also responsible for maintaining a public database of safety information for all registered substances. Under REACH laws, substances go through a four-part process:

1. Registration

Companies that manufacture, import or supply products with substances in quantities of one ton per year or more are required to register with ECHA. Registration includes preparing a technical dossier and a chemical safety report.

2. Evaluation

The European Chemicals Agency and Member State Competent Authorities evaluate all registered substances and dossiers to assess potential hazards or risks.

3. Authorization

Chemicals containing Substances of Very High Concern (SVHC), such as Polybutylene Terephthalate (PBT), as well as substances which are Very Persistent and Very Bio-accumulative (vPvBs), and/or identified as posing serious health hazards to humans or to the environment, are subject to authorization. Companies are required to submit plans to replace SVHC substances with safer alternatives. Currently, there are 163 SVHCs under the REACH regulation (See Figure C).

4. Restriction

Chemical substances that pose unacceptable or uncontrollable human health or environment risks may be restricted from the EU.

While REACH legislation applies to the majority of substances manufactured and/or imported within the EU, there are some exceptions and special provisions.
For instance, medicinal and veterinary products are exempt from registration. Other exemptions include radioactive substances, substances under customs supervision and those used in the interest of defense.

Complying with REACH

REACH regulations state that it is the responsibility of the manufacturer or importer to know the chemical composition of each of their products and to prove the safety of all substances used. For many companies this is a daunting task.

The cost of non-compliance is difficult to calculate but can be significant. Fines and penalties vary by country, and by the level of offense. But fees represent only a small portion of the price for compliance failure—hidden costs can take a toll. For instance, non-compliance can result in litigation, public relations issues, lost market share, and overall business disruption. In addition, companies that must remove a product from the market face lost sales and revenues. Costs can also be incurred to design, manage, test and launch new products that are compliant. To avoid potentially significant impacts to revenues, companies should not take a chance of being non-compliant and be thoroughly educated on the provisions, rules, and processes of REACH.

Figure B - SVHC additions over the years
Any company using chemicals in their products and exporting to the EU must be familiar with European chemical hazard classifications and clearly identify all substances being used to ensure REACH compliance. This can be achieved by establishing a sound and reliable inventory and, as new substances are added to the regulation, reviewing and updating records on a regular basis. Each substance should also be identified using a Chemical Abstracts Service (CAS) or European Commission number, along with information about how much of the substance is being exported. For companies that use mixtures of substances, the chemical composition of these mixtures must be known, as well as the manufacturer of each of the substances.

REACH regulations also require companies work with an EU subsidiary to meet registration and other requirements. While appointing representatives or outsourcing the compliance process are also acceptable methods, the original equipment manufacturer must play an active role during the substance pre-registration and registration processes. Regulations also require that companies maintain REACH-compliant documentation for 10 years after the release of a product.

RoHS2 and REACH: Here to Stay

For manufacturers and importers, understanding and complying with RoHS and REACH will remain a challenging and ever-changing issue—especially as more and more countries adopt similar regulations. Moreover, as public pressure mounts to add more substances faster under REACH, companies will be pressured to stay up to date with new registration rules and deadlines. In response, forward-thinking companies are making safer products with fewer hazardous chemicals. Most are proactive about compliance, as well as understanding new changes to the laws. And to help ensure compliance with RoHS and REACH, many companies take advantage of electronic component databases such as those provided by SiliconExpert Technologies. Because as costly and time-consuming as RoHS and REACH legislation may be, they are here to stay.
Founded in 2000, SiliconExpert Technologies has built the world’s largest electronic components database from scratch and provides this data through custom built software tools to the electronics industry. SiliconExpert’s software and data are used daily by thousands of electronic engineers, supply chain and procurement managers at leading Fortune 500 companies.

With over 400 employees worldwide, SiliconExpert maintains a global presence for its wide range of customers spanning Asia, Europe and Americas, operating in innovative industries such as consumer electronics, telecommunications, automotive, medical and aerospace.