

## Compliance with the EU's RoHS2, REACH and WEEE2 Directives

The European Union's RoHS2, REACH and WEEE directives have significant compliance and financial implications for companies wanting to market their products in Europe. The intent of all three directives is to control the use and disposal of substances that are hazardous to human health or to the environment. From design to disposal, the three directives impose regulations on an OEM's products over their entire lifecycle, and impact the OEM's supply chain, customers, distributors and dealers.

### Compliance with RoHS2

A CE Mark Directive

European Union Directive 2011/65/EU, RoHS Recast  
Effectivity Date January 2, 2013

The original version of the RoHS (Restriction of Hazardous Substances) Directive identified 6 substances that were hazardous to the environment and human health, and banned the sale of any electrical or electronic equipment that contained more than a threshold level of any of those substances:

RoHS2 Restricted Homogenous Substance Maximum Threshold Levels by Weight					
Lead (Pb)	Mercury (Hg)	Hexavalent Chromium (Cr)	Polybrominated Biphenyl (PBB)	Polybrominated Diphenyl Ether (PBDE)	Cadmium (Cd)
0.1%	0.1%	0.1%	0.1%	0.1%	0.01%
1000 ppm	1000 ppm	1000 ppm	1000 ppm	1000 ppm	100 ppm

While the RoHS2 Directive does not add any additional restricted substances, it does introduce several important changes to the original legislation. Among these changes are the following:

- 1) **Expansion of the Regulated Categories of Electrical and Electronic Equipment from 8 to 11** – Under the new directive, certain categories of electrical equipment that were exempted from the original directive, including medical devices and monitoring and control instruments, are now required to comply by certain dates that extend until July 22, 2019.

- 2) **CE Mark Requirement** - RoHS2 compliance is now a requirement for obtaining a CE Mark.
  
- 3) **Requirement for Evidence of Compliance** – The original equipment manufacturer must create a technical documentation file that provides evidence of compliance with RoHS2, including evidence of supply chain compliance. In 2011 European Standard *EN 50581:2012 “Technical documentation for the evaluation of electrical and electronic products with respect to restriction of hazardous substances”* was released to provide additional guidance to OEMs to meet this requirement. To encourage the use of this additional standard Article 16 (2) of the RoHS2 directive states that evidence of compliance with *EN 50581:2012* is sufficient to meet the ROHS2 requirement for technical documentation.

**Compliance with REACH**  
A CE Mark Directive  
EC1907/2006  
Effectivity Date June 1, 2008

Among the three directives, REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) is the most complex, regulating the use of over 1,000 (and growing) substances that are hazardous to human health or to the environment. REACH established the European Chemicals Agency (ECHA) to manage the technical and administrative aspects of the Directive.

- 1) **The Basics** – The Directive imposes limitations on the chemical content of all homogenous parts (capable of being mechanically separated). Uses of certain substances can be:
  - a) *Prohibited* entirely;
  - b) *Authorized* use through an application, review and approval process, but otherwise prohibited;
  - c) *Restricted* to a threshold percent concentration by weight;
  - d) *Reportable* (but not yet subject to authorization or restriction) in concentrations above 0.1% concentration by weight , and
  - e) *Transitional*, reportable but will require authorization after a certain sunset date.

- 2) **Additional considerations** –To further complicate the above material content limitations, requirements can vary within the EU by item, industry, application, and country of sale. In addition the directive is updated every six months. New substances can be added, and existing controlled substances in can be moved into a more restricted category.
- 3) **OEM and Supply Chain Impact**
  - a. **Regulatory burden** – At a minimum an OEM wanting to export a new device into the EU must:
    - Understand the chemical composition of each homogenous (capable of being separated mechanically) subassembly and component by gathering content data from the entire supply chain.
    - Determine which subassemblies and components are composed of substances controlled under REACH and their category (prohibited, authorized, restricted, reportable and transitional).
    - Depending on the regulatory burden and risk the OEM is willing to assume, source alternates for subassemblies and components that contain substances that are prohibited, authorized, or restricted.
    - Assuming the OEM can source subassemblies and components that contain only Reportable or Transitional Materials (and this is usually the case), submit the appropriate reports (can be as simple as the substance name and % content).
    - Note that some countries require suppliers to provide separate material declarations directly to the regulatory body (with suppliers subject to regulatory violations and fines); while most require the OEM to provide a single material declaration that covers the entire device, with the OEM bearing the entire regulatory burden and liability.
  - b. **OEM Risk Reduction** – Due to the complexity of the REACH Directive, the cost of compliance, and potential regulatory liability, an OEM should consider seeking expert advice before attempting to comply with the directive.

**Compliance with WEEE2**  
European Union Directive 2012/19/EU, WEEE Recast  
Effectivity Date February 14, 2014

The intent of the original WEEE (Waste Electrical and Electronic Equipment) Directive was to require manufacturers, distributors and retailers to finance the collection, treatment, recovery and environmentally-sound disposal of WEEE and to facilitate such activities through proper labeling.

WEEE2 introduces several changes to the original directive, including the following:

- Widens the scope of the WEEE directive to include additional equipment categories. As an example, printer cartridges containing electrical parts are now covered by the directive.
- Increases recycling, reuse and collection targets to further reduce the environmental impact of WEEE.

WEEE2 imposes no direct regulatory requirements on a manufacturer's suppliers and is not a CE Mark directive.

### Additional Resources

- [RoHS2](#)
- [REACH](#)
- [WEEE](#)