



ROHS II: MEET THE COMPLIANCE CHALLENGE

EXPLORE THE EXTENDED SCOPE AND REQUIREMENTS OF THE EUROPEAN UNION'S
NEW DIRECTIVE ON RESTRICTED SUBSTANCES, AS AMENDED BY DIRECTIVE 2015/863

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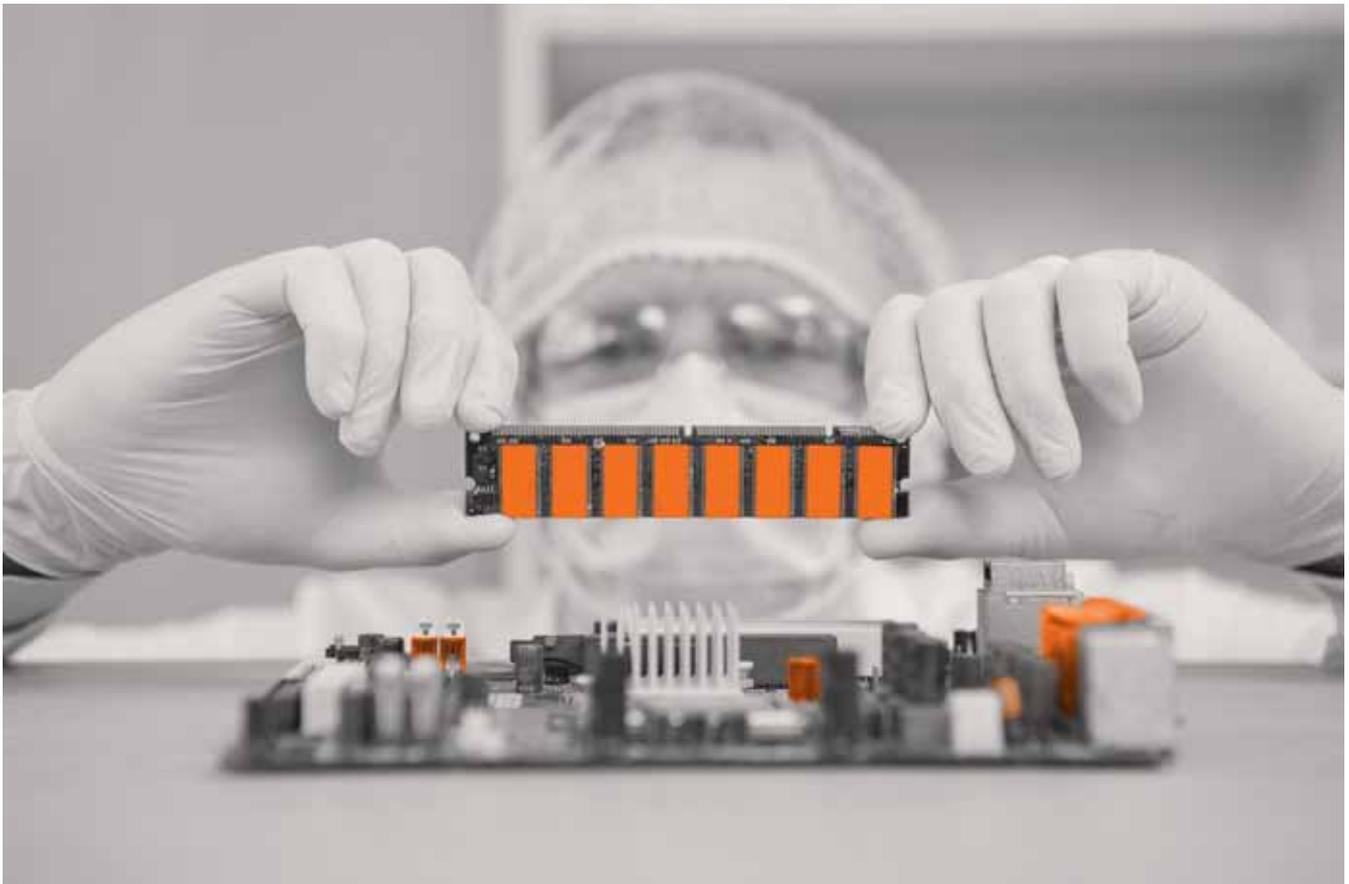
WHAT MANUFACTURERS NEED TO KNOW ABOUT THE EXPANDED SCOPE OF ROHS II

The European Union's updated legislation governing the Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive 2011/65/EU, also known as RoHS II (2011/65/ EU), and amended by Directive 2015/863 features significant changes in scope, with the addition of new restricted materials and legal responsibility.

Among the new mandate's changes are:

- The addition of an eleventh product category that expands coverage to any electrical or electromagnetic product
- The inclusion of previously excluded items, such as Medical Devices, In Vitro Medical Devices, Monitoring Control Instruments, Industrial Monitoring and Industrial Control Instruments
- The addition of 4 new restricted substances added by Directive EU 2015/863
- The requirement that manufacturers issue a signed Declaration of Conformity
- The requirement that manufacturers create a Technical Documentation File as per EN 50581:2012 or equivalent
- The acceptance of analytical material test results as per the IEC 623321 Standard
- The requirement to keep the DoC and Technical Documentation File for 10 years after the product is placed on the market
- The expanded requirement for European "CE" marking, to indicate RoHS II compliance

SGS Consumer Testing Services' new white paper examines all these changes in detail, while providing expert advice for companies that will need to demonstrate compliance with RoHS II in order to continue importing and distributing in the EU.



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I. EXECUTIVE SUMMARY

New substances, plenty of new challenges

In May 2011, the European Union adopted updated legislation governing the Restriction of Hazardous Substances in Electrical and Electronic Equipment (2011/65/EU).

The new directive as amended by Directive 2015/863 carries changes in scope, additional documentation requirements, adding of 4 new restricted materials, CE marking requirements and legal responsibilities defined for Importers and Distributors, in addition to manufacturers responsibilities that will impact a greater number of businesses than ever before.

Among the significant changes are:

- The addition of a new, eleventh product category that effectively expands coverage to manufacturers of any product that depend on electric currents or electromagnetic fields to fulfill at least one intended function
- The inclusion of Medical Devices, In Vitro Medical Devices, Monitoring and Control Instruments, Industrial Monitoring and Industrial Control Instruments
- The addition of four new restricted materials, starting as early as July 22, 2019
- The expanded meaning of the European "CE" marking, which will now indicate compliance with RoHS II in addition to other EU directives
- Resolution of problematic language from the original RoHS directive – namely, the meaning of "homogeneous material"

This white paper examines all of these changes in detail, while providing expert advice for companies who will need to demonstrate compliance with RoHS II in order to continue manufacturing, importing, distributing and placing on the market electrical and electronic equipment in any of the 28 EU member states.

II. THERE'S WORK TO BE DONE

Complying with the EU's RoHS II (2011/65/EU) directive is not a simple and straight forward task. RoHS II came into effect on January 3, 2013, and it will impact more manufacturers, suppliers, importers and distributors than RoHS I.

RoHS II – Restricted Substances and Allowable Levels and as amended by Directive 2015/863:

- **Lead (Pb): < 1000 ppm**
Commonly found in solder, lead-acid batteries, cable sheathing and cathode-ray tubes
- **Mercury (Hg): < 1000 ppm**
Typically found in batteries, switches and thermostats, and fluorescent lamps
- **Cadmium (Cd): < 100 ppm**
Most often present in car batteries and pigments
- **Hexavalent Chromium (Cr VI): < 1000 ppm**
Often used as an anti-corrosion agent in surface coatings, plating, and pigments and paints
- **Polybrominated Biphenyls (PBB): < 1000 ppm**
Commonly used as a flame retardant
- **And as amended starting on July 22, 2019 for categories 1 to 7, 10 and 11, and July 22, 2021 for categories 8 and 9**
 - Bis (2-ethylhexyl)phthalate (DEHP)
 - Butyl benzyl phthalate (BBP)
 - Dibutyl phthalate (DBP)
 - Diisobutyl phthalate (DIBP)

III. WHAT'S NEW IN ROHS II

Before companies can define their strategy for complying with RoHS II, they need to understand the key changes associated with the new directive:

(1) EXPANDED SCOPE

The RoHS II Directive includes 11 categories (Cat) of Electrical and Electronic Equipment (EEE):

- **Cat 1.** Large household appliances
- **Cat 2.** Small household appliances
- **Cat 3.** Computing & communications equipment
- **Cat 4.** Consumer electronics: TVs, DVD players, stereos, video cameras
- **Cat 5.** Lighting: lamps, lighting fixtures, light bulbs
- **Cat 6.** Power tools
- **Cat 7.** Toys and sports equipment
- **Cat 8.** Medical Devices starting July 22 2014; In Vitro Medical Devices starting July 22 2016
- **Cat 9.** Monitoring and Control Instruments starting July 22 2014; Industrial Monitoring and Industrial Control Instruments starting July 22 2017
- **Cat 10.** Automatic dispensers
- **Cat 11.** Other EEE not covered by any of the categories above (Categories 1-10) starting July 2019

The definition of EEE has been broadened to include any product that requires electric currents or electromagnetic fields to "fulfil" at least one intended function." Together, these changes have significant implications: Products that were formerly not covered by RoHS must now adhere to RoHS II.

Examples of Products Now Covered Under RoHS II

- Portable X-Ray Fluorescence Spectrometers
- Magnetic Resonance Imaging Equipment
- Portable Emergency Defibrillators
- Computerised Tomography Machines
- Smoke Detectors



(2) ADDITIONAL NEW RESTRICTED MATERIALS ADDED

The four added materials have a maximum concentration limit of 0.1% weight by weight of the homogeneous material they are contained in. These new materials are currently listed as SVHCs in REACH and need to be disclosed if they are found to be contained in excess of 0.1% weight of the articles they are contained in. The new materials may be found in items such as plastic connectors or plastic enclosures.

(3) EXPIRATION OF EXEMPTIONS

The original RoHS directive excluded several types of EEE identified in categories 8 and 9 (including certain types of medical and heavy industrial equipment). The new directive included categories 8 and 9, and will come into scope on a rolling timetable.

Among the affected items are:

- **Cat 8:** Medical Devices – including Magnetic Resonance Imaging (MRI) machines and Computerized Tomography (CT) machines starting July 22, 2014
- **Cat 8:** In Vitro Medical Devices – including polymerase chain reaction (PCR) equipment starting July 22, 2017
- **Cat 9:** Monitoring and Control Instruments – including smoke detectors, thermostats and hand-held thermometers starting July 22, 2014
- **Cat 9:** Industrial Control & Industrial Monitoring Instruments – including heating regulators and scanning electron microscopes starting July 22, 2017

By July 22, 2019, all exemptions will have expired, except for the following devices which remain out of scope for RoHS II:

- Equipment for security of Member States (for military purposes)
- Equipment designed to be sent into space

- Equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive
- Large-scale stationary industrial tools
- Large-scale fixed installations
- Means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved
- Non-road mobile machinery made available exclusively for professional use
- Active implantable medical devices
- Photovoltaic panels for permanent use at a defined location to produce energy from solar light for public, commercial, industrial and residential applications
- Equipment specifically designed solely for the purposes of R&D only made available on a business-to-business basis

(4) REQUIRED CE MARKING

Since 1993, the CE mark (Conformité Européenne) has been a mandatory symbol affixed to products to show compliance with an array of EU health, safety and environmental requirements – including the Low Voltage Directive (2006/95/EC), the Electromagnetic Compatibility Directive (2005/108/EC) and others. The symbol will also indicate

compliance with RoHS II, and all supporting CE documentation including conformity assessments, declarations and technical files must also include proof of restricted substance compliance as demonstrated by EN 50581:2012 and supporting analytical data as per IEC 62321 Standard.

(5) FURTHER DEFINITION OF “HOMOGENEOUS MATERIAL”

In the original directive, the limits on restricted substances were based on their concentration in “homogeneous material”. However, the term itself was not clearly defined, creating confusion for manufacturers. The new directive corrects this oversight by introducing a definition of “homogeneous material”:

“One material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be mechanically disjointed into different materials, meaning that the materials cannot be separated by mechanical actions such as unscrewing, cutting, crushing, grinding or abrasive processes.”

IV. IMPLICATIONS FOR NEWLY COVERED COMPANIES

The biggest challenges under RoHS II will undoubtedly be faced by companies that were not in scope of the original directive. Since January 3, 2013, these companies have had to demonstrate full conformity to Directive 2011/65/EU.

In the case of RoHS II, there are two primary options:

- 1) Gathering declarations of conformity and or full material composition data, from every material, component, sub-assembly supplier, outsourced design and manufacturer, and contract manufacturer along the supply chain for every material contained in the finished product
- 2) Having complete RoHS chemical testing performed as per IEC 62321 Standard due to a lack of supplier information or lapses in the quality or integrity of the data

Declarations of Conformity from the Supply Chain

In this approach, an EEE manufacturer would need to obtain a current Declaration of Conformity document from every supplier (of raw materials, sub-assemblies and more) associated with the creation of its product. In addition, declarations would be needed from any sub-contractors used by direct suppliers.

There are some obvious challenges with this approach. Not only is it extremely labour intensive, but it also places the legal responsibility squarely on the manufacturer's shoulders. The company can be held accountable if a supplier's technical data are out of date or inaccurate. It is also important to remember that contamination does not need to result from a deliberate action. Something as simple as a spill when mixing paint could increase the concentration of a hazardous substance.

However, for some manufacturers this approach can be a sensible, even cost-effective, option. It is best suited for companies making small pieces of equipment with few components or parts and those who manufacture their products in very limited quantities.

Declaration of Conformity...Defined

A self-generated document stating that the requirements of RoHS II have been met. When best practices are followed, it is supported by technical data kept on file at the company's offices.

Risk-Based Approach (Up to and Including Complete Testing of Finished Product)

In this approach, the manufacturer would commission a certified laboratory or testing facility to test the supplied material or finished product for the presence of hazardous substances.

Sometimes complete testing is necessary, where the product is broken down into its smallest "homogeneous" components. In many cases, however, the process can be strategically expedited by:

- 1) Testing only the parts that would logically use a restricted substance, or
- 2) Testing only for those substances that would likely be found in such a product. For example, it isn't necessary to test for PBDE, a flame retardant used in circuit boards, in a product that does not have complex circuitry. Of course, this approach also has its challenges. Manufacturers must first find an accredited facility that can handle the necessary tests, and then incur the expense of testing.

V. IMPLICATIONS FOR CURRENTLY COVERED COMPANIES

While companies new to the restricted substances directive will have the biggest compliance burdens, manufacturers already adhering to RoHS have work ahead of them, as well.

Ensuring Compliance Documentation is Up to Date

Of particular concern is the new application of the CE marking. Manufacturers need to ensure that the necessary data on restricted substances are included in all technical files – their own and their suppliers'.

In addition, further testing and documentation may be necessary. Most industry experts agree that compliance is not a one-time challenge. Conformity to directives, like RoHS II, should be constantly updated due to changes in material composition, expiration of exemptions, and each time a new supplier or component is added to the product Bill of Materials. Compliance data must be saved for 10 years after the product is put on the EU market.

Understanding the Consequences of Non-compliance

Because it's up to each EU member state, as well as some non-governmental bodies, to enforce directives like RoHS II, the consequences of non-compliance can vary widely. It is worth noting that penalties in some nations include the possibility of incarceration and fines as high as USD 69,555 (EURO 50,000).

Perhaps even more concerning are the business impacts. Companies that are found to be importing/exporting, distributing, selling or producing non-compliant EEE can face large-scale product recalls executed at their own expense – and a substantial loss of market share while their items are off the shelves. What's more, these costs can be compounded by damage to their brand image and the loss of goodwill with distributors/resellers and consumers.

CONSEQUENCES

- Penalties
- Loss of market share
- Expensive product recalls
- Damage to the brand image
- Loss of reputation
- Decline in sales

VI. HOW SGS CONSUMER TESTING SERVICES CAN HELP

It's clear that complying with RoHS2, as amended by Directive EU 2015/863, is challenging. The new challenges that RoHS2 has brought about are for example:

- Products out of scope now in scope
- Compiling technical documentation
- Training suppliers
- CE marking
- Checking for new materials

SGS is able to provide expert support for RoHS compliance. As part of SGS, the world's leading verification, testing and certification company, we specialize in partial and complete testing of finished products, and offer options for non-destructive testing. Our RoHS related services include:

- Product Risk Assessment
- Process Gap Analysis and Consulting
- Full Product and Material Testing to IEC 62321 standards
- XRF Screening
- RoHS Certificate of Conformity
- Verification Services
- Training
- REACH
- SVHC
- Ecodesign
- Energy Related Products (ErP)

WHY SGS?

- With more than 90 years experience we have a deep understanding of hazardous substances
- We operate more than 36 accredited RoHS testing centres worldwide staffed by more than 1,000 RoHS specialists in over 20 countries
- Furthermore, we offer:
 - Rapid turnaround times
 - Value-based pricing
 - Technical assistance
 - Key account management

No matter where your production facility is located, there's likely to be an SGS facility near you.

Uniquely, our range of services includes the only globally accepted database of RoHS certification reports. Known as the RoHS Certificate of Conformity, this service ensures your ability to do business throughout the EU with confidence.

As you consider your company's compliance challenges, let SGS help you make the best decisions for your business.



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¹ 2008 study by Technology Forecasters Inc. for the Consumer Electronics Association ² RoHSGuide.com ³ Compiled by SGS Chemical Lab, Taiwan

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WHEN YOU NEED TO BE SURE

