RoHS2 Directive Officially in Effect

July 2011 the Recast RoHS Directive was published in the Official Journal by the European Commission, which now makes it a legal document you need to comply with.

Unless your products are specifically listed as one of the exemptions, with time it will apply to every manufacturer of electrical and electronic equipment.

Products already covered by the original 8 categories have a transition period of 2 January 2013 to meet the requirements of the Recast Directive.

New categories formerly excluded but now included:
- In-vitro Diagnostic Medical Devices – 5 Years – 22 July 2016.
- Active Implantable Medical Devices – Will be reviewed in 2020 for inclusion.

All other electrical and electronic equipment not covered by any of the categories above – 22 July 2019.

The most important change

The Recast RoHS Directive is now a CE-marking directive. In plain English, what this means is that if you manufacture an electrical/electronic product, device or equipment, you can no longer CE-mark in accordance with just the Medical Device, Machinery, EMC or Low Voltage Directive. Compliance with the RoHS Directive is required before you can place the CE mark on the product. This should be obvious on your Declaration of Conformity.

RoHS2 Directive And Definitions


The RoHS2 Directive refers to a secondary document where you can locate the procedures for assessing the conformity of EEE, it is Decision no. 768/2008/EC on a Common framework for the marketing of products. Please download this document from the following link: http://www.ce-mark.com/7682008EC.pdf

As a first step in the compliance process you need to know if the RoHS2 Directive applies to your products, let’s start with the definition below:

The definition of “EEE” or Electrical and Electronic Equipment is: “Electrical and electronic equipment” means equipment which is dependent on electrical currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage not exceeding 1000 Volts for Alternating Current and 1500 Volts for Direct Current.

Additional definitions you may want to read can be found as follows in the RoHS2 Directive: Article 3- definitions. Pages L174/91 and 92, (1) through (28).
Here are a few examples:

(3) 'large-scale stationary industrial tools'
(4) 'large-scale fixed installations'
(5) 'cables'
(6) 'manufacturer'
(7) 'authorized representative'
Etc.

Substances and Product Categories

A) The six hazardous and restricted substances in the RoHS2 directive are outlined in Annex II (page L174/100) with maximum concentration values tolerated by weight to homogeneous materials. They are:

1) Lead (0.1%)
2) Mercury (0.1%)
3) Cadmium (0.01%)
4) Hexavalent chromium (0.1%)
5) Polybrominated biphenyls (0.1%)
6) Polybrominated diphenyl ethers (PBDE) (0.1%)

The good news is that these are the same substances listed in the RoHS Directive prior to RoHS2.

B) Before the recast there were 8 categories of products as follows:

1) Large Household appliances
2) Small Household appliances
3) IT and Communications equipment
4) Consumer Equipment
5) Lighting equipment
6) Electrical and electronic tools
7) Toys, leisure and sports equipment
10) Automatic Dispensers

These 8 product categories must implement the changes published in the RoHS2 directive no later than 2 January 2013. All EU States must have adopted and published RoHS2 into National Law by the same date. See article 25: Transposition on page L174/98.

After the recast, RoHS2 adds 3 product categories with specific deadlines, they are:

11) All other electrical and electronic equipment not covered by any of these categories – deadline 22 July 2019.

An observation about the deadlines. They are legal enforcement dates, however, commercially, importers start asking for compliant product at least 6 months prior to the legal deadline, in order not to end up with non-compliant product in inventory. You may want to consider this in your implementation timeline.

Exemptions

Exemptions to the RoHS2 Directive can be divided into 3 groups:

I) Equipment and products this directive does not apply to, in Article 2 Point 4 (page L174/91) and Article 4 Points 4 and 5 (page L174/93)

II) General exemptions listed in Annex III (pages L174/101 through 105)

III) Exemptions specific to medical devices and monitoring and control instruments in Annex IV (page L174/106)

Recommendation

We strongly recommend that you read all exemptions as stated in the Directive plus Article 5 point 3 (page L174/93) combined with Annex V (page L174/107) where you can find the information and details on how to apply for an exemption.
Who Is responsible For What

Compliance with the RoHS2 directive is the responsibility of the Economic Operators, they are:
1) Manufacturer 
2) Authorized Representative 
3) Importers 
4) Distributors

RoHS2 outlines each parties specific responsibilities in Articles 7,8,9, and 10.

Module A of Annex II in Decision 768/2008/EC point 2. Technical documentation (read technical file)
The manufacturer shall establish the technical documentation.
The documentation shall make it possible to assess the product's conformity to the relevant requirements and shall include an adequate analysis and assessment of the risk(s).
The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product.
The technical documentation shall, where applicable, contain at least the following elements:
- a general description of the product,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- descriptions and explanations if necessary of those drawings and schemes and the operation of the product,
- a list of the harmonized standards and/or other relevant technical specifications the references of which have been published in The Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonized standards have not been applied. In the event of partly applied harmonized standards, the technical documentation shall specify the parts which have been applied, results of design calculations made, examinations carried out, etc., and test reports

Module A of Annex II in Decision 768/2008/EC point 1, 3 and 4 Internal Production Control (Quality Product System)
1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfills the obligations laid down in points 2,3 and 4, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.
2. Technical documentations (see above).
3. Manufacturing
The manufacturer shall take all measures necessary so
that the manufacturing process and its monitoring en-
sure compliance of the manufactured products with the
technical documentation referred to in point 2 and with
the requirements of the legislative instruments that ap-
ply to them.

4. Conformity marking and declaration of conformity.
The CE- Mark shall be affixed visibly, legibly and indel-
bly to the finished EEE or to its data plate.
4.1 The manufacturer shall affix the required conformity
marking set out in the legislative instrument to each
individual product that satisfies the applicable require-
ments of the legislative instrument.
4.2 The manufacturer shall draw up a written declara-
tion of conformity for a product model and keep it to-
gether with the technical documentation at the disposal
of the national authorities for 10 years (through its
authorized representative) after the product has been
placed on the market. The declaration of conformity
shall identify the product for which it has been drawn up.
A copy of the declaration of conformity shall be made
available to the relevant authorities upon request.

Special Note:
Notified Body assessment and certification is not a
requirement of this directive.

Enhanced Legal Standing
The statement you will hear most in the future is: RoHS2
is now a CE-marking directive.

Here is what it means to:
I. All EU Countries:
Each EU country must adopt the RoHS2 directive into
National law by 2 January 2013. This is the date they
are obliged to start enforcement which is referred to as
market surveillance.
II. All EEE Manufacturers:
In order to place a CE-mark on your EEE products you
must meet the requirements of all applicable directives,
this now includes RoHS2.

Example 1: If you manufacture machinery with
electrical/electronics (EEE) and in the past you CE-marked
in accordance with the Machinery Directive + EMC Direc-
tive, starting 2 January 2013 you need to comply with:
Machinery + EMC + RoHS2. All three directives must be
on your Declaration of Conformity.

Example 2: If you manufacture electrical/electronic (EEE)
medical devices and in the past you CE-marked in accord-
dance with the Medical Device Directive, starting 22 July
2014 you need to comply with the Medical Device Directive
+ RoHS2. Both directives must appear on your Declaration
of Conformity.
(Until your products fall under one of the exempt-
tions)

Ill. All EEE Importers and Distributors:
Must ensure that all EEE products they import and place
on the EU market complies with RoHS2.

IV. All Authorized Representatives:
Must keep the Declaration of Conformity and technical
documentation demonstrating compliance with RoHS2 at
the disposal of the national surveillance authorities for 10
years following the placing on the market of EEE.

Enforcement – Better Known as
Market Surveillance

The Surveillance Authority in each EU Member State:
In article 18 of the RoHS2 Directive the European Commis-
sion instructs all EU Member States to carry out market
surveillance in accordance with Articles 15 to 29 of Regu-
lation (EC) No. 765/2008 relating to Community Market
Surveillance Framework and Control of Products entering
the Community Market. You can download a copy of the
document here:
http://www.ce-mark.com/Regulation%20765%202008.pdf
A few examples of the activities the Surveillance Authority
are obliged to carry out are:
- Must ensure that products which do not comply with
applicable directives to be withdrawn, prohibited or restrict-
ed from the EU market.
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What Manufacturers Need To Know And Do

- Must have procedures to: 1) follow up on complaints or reports; 2) monitor accidents and harm to health; 3) verify that corrective action has been taken; 4) follow up scientific and technical knowledge concerning safety issues.

- Shall perform appropriate checks by means of documentary checks, physical and laboratory checks based on adequate samples. Taking into account risk assessments, complaints and other information.

- May require the economic operators to provide documentation and information, and where is necessary and justified they may enter the premises and take necessary samples.

- May destroy products presenting a serious risk,

- Shall observe confidentiality in order to protect commercial secrets or personal data

- Work with the EU Commission to place the information on the Community Rapid Information System, notifying all EU Countries where products have been sold.

- Must cooperate with external border control authorities. (Customs).

- Shall lay down the rules on penalties applicable to infringements and shall make sure that they are implemented. They must be effective, proportionate, and dissuasive.

Economic Operators:

Importers:
If they have reason to believe that an EEE is not in conformity with RoHS, they must 1) not place it on the market until it has been brought into conformity; 2) Must inform the manufacturer and the market surveillance authority.

Distributors:
If they have reason to believe that an EEE is not in conformity with RoHS, they must 1) not place it on the market until it has been brought into conformity; 2) Must inform the manufacturer or the importer and the market surveillance authority.

Authorized Representative:
Must provide the Market Surveillance Authority with all the information and documentation (including Declaration of Conformity) necessary to demonstrate conformity with RoHS2 on behalf of the manufacturer.

What Are We Waiting For?
Every European CE-marking Directive comes with a list of references of harmonised standards. However no harmonised standards for the RoHS2 Directive have been published in the Official Journal as yet.

There are some non-harmonised standards that do exist and provide some useful guidance relating to material restrictions, they are:

- IEC TR 62476: Guidance for evaluation of products with respect to substance-use restrictions in electrical and electronic products.
- EN 62321: Electrotechnical products – Determination of levels of six regulated substances (lead, mercury, cadmium, Hexavalent chromium, Polybrominated biphenyls, Polybrominated diphenyl ethers)
- IEC 62474 (DRAFT STAGE): Material declaration for products of and for the Electrotechnical Industry
- IECQ QC 080000: Hazardous Substances Process management (HSPM)

We do not know if any of these standards will become Harmonised Standards.

Work is ongoing with CENELEC (European Committee for Electrotechnical Standardization) to better define the content of the technical file documentation with specific reference to the RoHS2 Directive.

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