RoHS2 DIRECTIVE 2011/65/EU

What Manufacturers Need To Know And Do

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:
Medical Devices – 3 Years – 22 July 2014.
In-vitro Diagnostic Medical Devices – 5 Years – 22 July 2016.
Monitoring and Control Instruments – 3 Years – 22 July 2014.
Industrial Monitoring and Control Instruments – 6 Years – 22 July 2017.
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.

QNET LLC
PO Box 527
Elk River, MN 55330
763-441-0899

http://www.CE-Mark.com

http://www.CE-Authorizedrepresentative.eu

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

Please download the new RoHS2 Directive officially titled: Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. Here is the link:
http://www.ce-mark.com/Rohs%20final.pdf
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).

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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:

8) Medical devices – deadline 22 July 2014, including In-Vitro Diagnostic medical devices – deadline 22 July 2016.

9) Monitoring and Control Instruments – deadline 22 July 2014, including Industrial Monitoring and Control Instruments – deadline 22 July 2017.

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.

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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.

Compliance - Including Supply Chain

The manufacturer shall in accordance with Article 7:
(a) Ensure that the product has been designed and manufactured in accordance with Article 4.
(b) Draw up the required technical documentation (technical file) and carry out the internal production control procedure in accordance with Module A of Annex II in Decision 768/2008/EEC.
(c) Ensure that procedures are in place for series production to remain in conformity.
(d) Keep a register of non-conforming EEE and product recalls, and keep distributors informed thereof.
(e) Ensure that their EEE bears a type, batch or serial number.
(f) Follow specific labeling requirements.
(g) Take corrective measures to bring the EEE into conformity, withdraw it from the market or recall it if they have a reason to believe that it is not in compliance with the RoHS2 Directive AND inform the Competent Authorities in all Member States where the EEE is available.
(h) Respond to a reasoned request from a Competent National Authority; provide all information and documentation to demonstrate conformity in a language which can be easily understood, through your Authorized Representative. And cooperate with that authority on taking any action to ensure compliance with this Directive.

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).

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3. Manufacturing
The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the legislative instruments that apply to them.
4. Conformity marking and declaration of conformity. The CE- Mark shall be affixed visibly, legibly and indelibly 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 requirements of the legislative instrument.
4.2 The manufacturer shall draw up a written declaration of conformity for a product model and keep it together 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 Directive, 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 accordance 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.
(**Unless your products fall under one of the exemptions**)

III. 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 Commission instructs all EU Member States to carry out market surveillance in accordance with Articles 15 to 29 of Regulation (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 restricted from the EU market.

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- 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.

· IEC/PAS 62596: Electrotechnical products – determination of restricted substances – Sampling procedure – Guidelines.

· 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.
