RoHS (including recast)

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- Product categories
- Substances
- Exemptions
- CE requirements

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Introduction to the requirements of the RoHS Directive 2002/95/EC

The Restriction of the use of certain Hazardous Substances (RoHS) Directive came into force on 1st July 2006. From this date, producers of eight categories of electrical and electronic equipment were not able to place on the market products that contain six "banned" substances unless specific exemptions apply. These six substances are:

- Lead - (Pb)
- Mercury - (Hg)
- Hexavalent chromium - (Cr(VI))
- Cadmium - (Cd)
- Polybrominated biphenyl flame retardants - (PBB)
- Polybrominated diphenyl ether flame retardants - (PBDE)

The Directive has applied to electrical and electronic equipment that is dependent on electric or electromagnetic fields in order to work properly. Also, equipment for the generation, transfer and measurement of such currents and fields falling within the 8 product categories listed below and designed for use with a voltage rating not exceeding 1,000 volts for alternating current and 1,500 volts for direct current. The scope has been eight of the ten categories of the Waste Electrical and Electronic Equipment (WEEE) Directive. These are:

1. Large household appliances
2. Small household appliances
3. IT and telecommunications equipment
4. Consumer equipment
5. Lighting equipment (including light bulbs, and luminaries in households)
6. Electrical and electronic tools (except large scale stationary industrial tools)
7. Toys, leisure and sports equipment

10. Automatic dispensers

Categories 8 (medical devices) and 9 (monitoring and control instruments) will be included in the scope as a result of the recast of RoHS described later.

What is a compliant product?

The RoHS Directive applies to equipment that is within the scope of the Directive. None of the "homogeneous materials" within compliant products must contain the six restricted substances at concentrations above the "maximum concentration values".

Who is responsible?

Currently "producers" of equipment are held responsible for ensuring that their products do not contain the six restricted substances. The Directive does not cover components or sub-assemblies and so the equipment producers will have to take their own steps to ensure that all parts and materials used in their products do not contain restricted substances.

"Producer" is defined as any person who, irrespective of the selling technique used:

i. manufactures and sells electrical and electronic equipment under his own brand;
ii. resells under his own brand equipment produced by other suppliers; or
iii. imports or exports electrical and electronic equipment on a professional basis into a member state.

It is clear from this that there will be circumstances in which it is not the manufacturer of a product who assumes the "producer" responsibilities. The responsibility for compliance with RoHS will broaden as a result of the recast as explained below.

What are the maximum concentration values (MCV)?

These are 0.1 % by weight of lead, mercury, hexavalent chromium, PBB and PBDE and 0.01 % by weight cadmium in homogeneous materials.

What is a homogeneous material?

A homogeneous material cannot be mechanically broken down (by cutting, grinding, crushing etc) into different materials - examples would be plastic, ceramic, glass, metal etc.

What Product Categories need to comply?

The list below includes examples of products that are in scope currently and also categories 8, 9 and 11 which will be brought into scope as a result of the recast. The list of products below each category heading is illustrative and not exhaustive

1. Large household appliances

(Such as large cooling appliances; refrigerators; freezers; other large appliances used for refrigeration, conservation and storage of food; washing machines; clothes dryers; dish washing machines; cooking; electric stoves; electric hot plates; microwaves; other large appliances used for cooking and other processing of food; electric heating appliances; electric radiators; other large appliances for heating rooms, beds, seating furniture; electric fans; air conditioner appliances; other fanning, exhaust ventilation and conditioning equipment)

2. Small household appliances

(Such as vacuum cleaners; carpet sweepers; other appliances for cleaning; appliances used for sewing, knitting, weaving and other processing for textiles; irons and other appliances for ironing, mangling and other care of clothing; toasters; fryers; grinders, coffee machines and equipment for opening or sealing of containers or packages; electric knives; appliances for hair-cutting, hair drying, tooth brushing, shaving, massage and other body care appliances; clocks, watches and equipment for the purpose of measuring, indicating or registering time; scales)

3. IT and telecommunications equipment

(Such as centralised data processing; mainframes; minicomputers; printer units; personal computing; personal computers, including the CPU, mouse and keyboard; laptop computers, including the CPU, mouse and keyboard; notebook computers; notepad computers; printers; copying equipment; electrical and electronic typewriters; pocket and desk calculators; other products and equipment for the collection, storage, processing, presentation or communication of information by electronic means; user terminals and systems; facsimile; telex; telephones; pay telephones; cordless telephones; cellular telephones; answering systems; other products or equipment of transmitting sound, images or other information by telecommunications)

4. Consumer equipment

Such as radio sets; television sets; video cameras; video recorders; hi-fi recorders; audio amplifiers; musical instruments; other products or equipment for the purpose of recording or reproducing sound or images, including signals or other technologies for the distribution of sound and image than by telecommunications)

5. Lighting equipment, (including electric light bulbs and household luminaries)

(Such as luminaries for fluorescent lamps; straight fluorescent lamps; compact fluorescent lamps; high intensity discharge lamps, including pressure sodium lamps and metal halide lamps; low pressure sodium lamps; other lighting equipment for the purpose of spreading or controlling light)

6. Electrical and electronic tools (with the exception of large-scale stationary industrial tools)

(Such as drills; saws; sewing machines; equipment for turning, milling, sanding, grinding, sawing; cutting; shearing; drilling; making holes; punching; folding; bending or similar processing of wood, metal and other materials; tools for riveting, nailing or screwing or removing rivets, nails, screws or similar uses; tools for welding, soldering or similar use; equipment for spraying, spreading, dispersing or other treatment of liquid or gaseous substances by other means; tools for mowing or other gardening activities)

7. Toys, leisure and sports equipment

(Such as electric trains or car racing sets; hand-held video game consoles; video games; computers for biking, diving, running, rowing, etc.; sports equipment with electric or electronic components; coin slot machines)

8. Medical

(Such as X-ray, MRI, CT, ultrasound, blood pressure monitors, radiotherapy, ECG, defibrillators, hearing aids, blood analysers, dental drill and medical freezers.)

9. Monitoring and control

(Such as instruments, analysis instruments, luggage X-ray, digital voltmeters)

10. Automatic dispensers

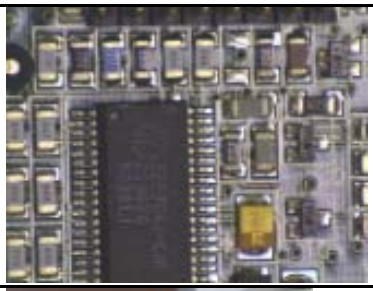
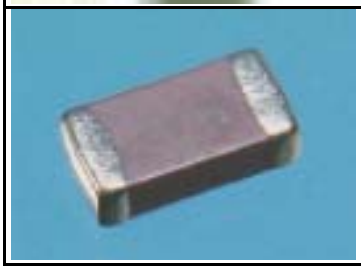
(Such as automatic dispensers for hot drinks; automatic dispensers for hot or cold bottles or cans; automatic dispensers for solid products; automatic dispensers for money; all appliances which deliver automatically all kind of products)

(This will include all products not captured in Categories 1 to 10, unless specifically excluded. While not the choice of all Member States, the open scope was one of several compromises reached to guarantee a first reading approval.)

11. Open Scope

Restricted substances -where they might be found

Substances	Application
Lead	Solders
	Termination coatings on components
	Paints as pigments and as driers
	PVC as a stabiliser
	Batteries (not covered by RoHS Directive)
Cadmium	Electroplated coatings
	Special solders (e.g. in some types of fuse)
	Electric contacts, relays, switches
	PVC stabiliser
	Plastics, glass and ceramic pigments
	In some glass and ceramic materials
Mercury	Lamps
	Sensors
	Relays
Hexavalent chromium	Passivation coatings on metals
	In corrosion resistant paints
PBB and PBDE	Flame retardants in plastics

	Potentiometer, may contain cadmium internally		Lead in solder or termination coating
	Lamp, glass and solder may contain lead		Plastic housings, PBB, PBDE, cadmium and lead
	Plastic connector and cable insulation may contain lead or cadmium		Electrolytic capacitor; lead in termination coatings and in plastic cover if PVC
	MLCC, lead in ceramic is exempt but lead in termination is banned		Cadmium or lead in plastic and lead in electroplated coatings

RoHS Directive - recent history

Changes to the RoHS directive.

Since the RoHS directive came into force in 2006, there have been changes to the exemptions and in 2010, the EU agreed to a range of changes to the directive, known as the "recast" and these will take effect during the following seven years.

Exemptions review:

All exemptions are temporary and the current procedure is to review all exemptions at least every four years. The current list of RoHS exemptions entered into force on 24th September 2010 and was correct on 29th September:

No.	Description	Expiry date
1	Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):	
1(a)	For general lighting purposes < 30 W: 5 mg	Expires on 31 December 2011; 3.5 mg may be used per burner after 31 December 2011 until 31 December 2012; 2.5 mg shall be used per burner after 31 December 2012
1(b)	For general lighting purposes ≥30 W and < 50 W: 5 mg	Expires on 31 December 2011; 3.5 mg may be used per burner after 31 December 2011
1(c)	For general lighting purposes ≥ 50 W and < 150 W: 5 mg	
1(d)	For general lighting purposes ≥150 W: 15 mg	
1(e)	For general lighting purposes with circular or square structural shape and tube diameter ≤17 mm	No limitation of use until 31 December 2011; 7 mg may be used per burner after 31 December 2011
1(f)	For special purposes: 5 mg	
2(a)	Mercury in double-capped linear fluorescent lamps for general lighting purposes not exceeding (per lamp):	
2(a) (1)	Tri-band phosphor with normal lifetime and a tube diameter < 9 mm (e.g. T2): 5 mg	Expires on 31 December 2011; 4 mg may be used per lamp after 31 December 2011
2(a) (2)	Tri-band phosphor with normal lifetime and a tube diameter ≥ 9 mm and ≤ 17 mm (e.g. T5): 5 mg	Expires on 31 December 2011; 3 mg may be used per lamp after 31 December 2011
2(a) (3)	Tri-band phosphor with normal lifetime and a tube diameter > 17 mm and ≤ 28 mm (e.g. T8): 5 mg	Expires on 31 December 2011; 3.5 mg may be used per lamp after 31 December 2011
2(a) (4)	Tri-band phosphor with normal lifetime and a tube diameter > 28 mm (e.g. T12): 5 mg	Expires on 31 December 2012; 3.5 mg may be used per lamp after 31 December 2012
2(a) (5)	Tri-band phosphor with long lifetime(≥ 25,000 h): 8 mg	Expires on 31 December 2011; 5 mg may be used per lamp after 31 December 2011
2(b)	Mercury in other fluorescent lamps not exceeding (per lamp):	
2(b) (1)	Linear halophosphate lamps with tube diameter > 28 mm (e.g. T10 and T12): 10 mg	Expires on 13 April 2012
2(b) (2)	Non-linear halophosphate lamps (all diameters): 15 mg	Expires on 13 April 2016
2(b) (3)	Non-linear tri-band phosphor lamps with tube diameter > 17 mm (e.g. T9)	No limitation of use until 31 December 2011; 15 mg may be used per lamp after 31 December 2011
2(b) (4)	Lamps for other general lighting and special purposes (e.g. induction lamps)	No limitation of use until 31 December 2011; 15 mg may be used per lamp after 31 December 2011
3	Mercury in cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for special purposes not exceeding (per lamp):	
3(a)	Short length (≤ 500 mm)	No limitation of use until 31 December 2011; 3.5 mg may be used per lamp after 31 December 2011
3(b)	Medium length (> 500 mm and ≤ 1,500 mm)	No limitation of use until 31 December 2011; 5 mg may be used per lamp after 31 December 2011
3(c)	Long length (> 1,500 mm)	No limitation of use until 31 December 2011; 13 mg may be used per lamp after 31 December 2011
4(a)	Mercury in other low pressure discharge lamps (per lamp)	No limitation of use until 31 December 2011; 15 mg may

No.	Description	Expiry date
		be used per lamp after 31 December 2011
4(b)	Mercury in High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner) in lamps with improved colour rendering index Ra > 60:	
4(b)-I	P ≤ 155 W	No limitation of use until 31 December 2011; 30 mg may be used per burner after 31 December 2011
4(b)-II	155 W < P ≤ 405 W	No limitation of use until 31 December 2011; 40 mg may be used per burner after 31 December 2011
4(b)-III	P > 405 W	No limitation of use until 31 December 2011; 40 mg may be used per burner after 31 December 2011
4(c)	Mercury in other High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner):	
4(c)-I	P ≤ 155 W	No limitation of use until 31 December 2011; 25 mg may be used per burner after 31 December 2011
4(c)-II	155 W < P ≤ 405W	No limitation of use until 31 December 2011; 30 mg may be used per burner after 31 December 2011
4(c)-III	P > 405 W	No limitation of use until 31 December 2011; 40 mg may be used per burner after 31 December 2011
4(d)	Mercury in High Pressure Mercury (vapour) lamps (HPMV)	Expires on 13 April 2015
4(e)	Mercury in metal halide lamps (MH)	
4(f)	Mercury in other discharge lamps for special purposes not specifically mentioned in this Annex	
5(a)	Lead in glass of cathode ray tubes	
5(b)	Lead in glass of fluorescent tubes not exceeding 0.2% by weight	
6(a)	Lead as an alloying element in steel for machining purposes and in galvanized steel containing up to 0.35% lead by weight	
6(b)	Lead as an alloying element in aluminium containing up to 0.4% lead by weight	
6(c)	Copper alloy containing up to 4% lead by weight	
7(a)	Lead in high melting temperature type solders (i.e. lead-based alloys containing 85% by weight or more lead)	
7(b)	Lead in solders for servers, storage and storage array systems, network infrastructure equipment for switching, signalling, transmission, and network management for telecommunications	
7(c)-I	Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound	
7(c)-II	Lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher	
7(c)-III	Lead in dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC	Expires on 1 January 2013 and after that date may be used in spare parts for EEE placed on the market before 1 January 2013
8(a)	Cadmium and its compounds in one shot pellet type thermal cut-offs	Expires on 1 January 2012 and after that date may be used in spare parts for EEE placed on the market before 1 January 2012
8(b)	Cadmium and its compounds in electrical contacts	
9	Hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0.75 % by weight in the cooling solution	
9(b)	Lead in bearing shells and bushes for refrigerant-containing compressors for heating, ventilation, air conditioning and refrigeration (HVACR) applications	
11(a)	Lead used in C-press compliant pin connector systems	May be used in spare parts for EEE placed on the market before 24 September 2010

No.	Description	Expiry date
11(b)	Lead used in other than C-press compliant pin connector systems	Expires on 1 January 2013 and after that date may be used in spare parts for EEE placed on the market before 1 January 2013
12	Lead as a coating material for the thermal conduction module C-ring	May be used in spare parts for EEE placed on the market before 24 September 2010
13(a)	Lead in white glasses used for optical applications	
13(b)	Cadmium and lead in filter glasses and glasses used for reflectance standards	
14	Lead in solders consisting of more than two elements for the connection between the pins and the package of microprocessors with a lead content of more than 80% and less than 85% by weight	Expires on 1 January 2011 and after that date may be used in spare parts for EEE placed on the market before 1 January 2011
15	Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages	
16	Lead in linear incandescent lamps with silicate coated tubes	Expires on 1 September 2013
17	Lead halide as radiant agent in high intensity discharge (HID) lamps used for professional reprography applications	
18(a)	Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as speciality lamps for diazoprinting reprography, lithography, insect traps, photochemical and curing processes containing phosphors such as SMS ((Sr,Ba)2MgSi2O7:Pb)	Expires on 1 January 2011
18(b)	Lead as activator in the fluorescent powder (1% lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP ($BaSi_2O_5$:Pb)	
19	Lead with PbBiSn-Hg and PbInSn-Hg in specific compositions as main amalgam and with PbSn-Hg as auxiliary amalgam in very compact energy saving lamps (ESL)	Expires on 1 June 2011
20	Lead oxide in glass used for bonding front and rear substrates of flat fluorescent lamps used for Liquid Crystal Displays (LCDs)	Expires on 1 June 2011
21	Lead and cadmium in printing inks for the application of enamels on glasses, such as borosilicate and soda lime glasses	
23	Lead in finishes of fine pitch components other than connectors with a pitch of 0.65 mm and less	May be used in spare parts for EEE placed on the market before 24 September 2010
24	Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors	
25	Lead oxide in surface conduction electron emitter displays (SED) used in structural elements, notably in the seal frit and frit ring	
26	Lead oxide in the glass envelope of black light blue lamps	Expires on 1 June 2011
29	Lead bound in crystal glass as defined in Annex I (Categories 1, 2, 3 and 4) of Council Directive 69/493/EEC	
30	Cadmium alloys as electrical/mechanical solder joints to electrical conductors located directly on the voice coil in transducers used in high-powered loudspeakers with sound pressure levels of 100 dB (A) and more	Currently under review
31	Lead in soldering materials in mercury free flat fluorescent lamps (which e.g. are used for liquid crystal displays, design or industrial lighting)	Currently under review
32	Lead oxide in seal frit used for making window assemblies for Argon and Krypton laser tubes	Currently under review
33	Lead in solders for the soldering of thin copper wires of 100 µm diameter and less in power transformers	
34	Lead in cermet-based trimmer potentiometer elements	

No.	Description	Expiry date
37	Lead in the plating layer of high voltage diodes on the basis of a zinc borate glass body	
38	Cadmium and cadmium oxide in thick film pastes used on aluminium bonded beryllium oxide	
39	Cadmium in colour converting II-VI LEDs (< 10 µg Cd per mm^2 of light-emitting area) for use in solid state illumination or display systems	Expires on 1 July 2014

Recast RoHS Directive

Scope

The recast directive will have an open scope with a list of exclusions. The open scope is any electrical and electronic product although with the current upper voltage limits. The scope is however divided into eleven categories. The reason for this is that there are different dates when RoHS obligations begin for categories 8, 9 and 11.

Category	Currently proposed dates
8 - Medical equipment (not IVD)	Three years after entry into force (2014)
8 – Medical equipment (IVD)	Five years after entry into force (2016)
9 – Monitoring & Control (Consumer)	Three years after entry into force (2014)
9 – Monitoring & Control (Industrial)	Six years after entry into force (2017)
11 – All EEE not captured in 1-10, unless specially excluded	Eight years after entry into force (2019)

In scope applies to products put on the market after these dates.

Article 3b

Previously RoHS scope applied to electrical and electronic equipment that is dependent on electric or electromagnetic fields in order to work properly. Now the recast states electronic equipment that is dependent on electronic or electromagnetic fields **to fulfil at least one of its intended functions**. Therefore a gas cooker which has an electric clock would now fall within scope where previously it would not. This small change could widen the amount of equipment that will now fall within scope.

Currently, the list of excluded products are:

- **Military and national security equipment**

  – not defined but the same as at present.

- **Large-scale stationary industrial tools (LSIT)**

  – these are large-scale manufacturing plant such as oil refineries, production lines, etc and this exclusion is the same as the current LSIT exclusion.

- **Transport for people and goods**

  – aircraft, trains, commercial vehicles, buses, vans, cars, ships and boats and any electrical equipment that is designed to be used as integral parts of these forms of transport. The only exception is two wheeled electric bicycles which will be in scope.

- **Equipment for use in space such as satellites**

  – previously assumed to be excluded so this clarifies the status.

- **Active implanted medical devices**

  – recommendation from ERA report (pacemakers, etc.)

- **Photovoltaics**

  – commercial electricity generation systems, not consumer products.

- **Mobile industrial machinery**

  – a new exclusion that covers only professional equipment so would exclude from the scope of RoHS some equipment such as commercial electric lawnmowers designed for golf courses and public spaces which are currently in scope.

- **Large-scale fixed installations**

  – a new exclusion which is intended to clarify the status of fixed installations. Currently the status of fixed installations is very unclear with each Member State having its own interpretation. However it is clear

that domestic smoke detectors are in scope, despite being screwed to ceilings whereas the status of fire detection systems which include smoke detectors used in large buildings is not clear (some countries include in scope whereas others exclude these). The main problem with this new exclusion is that "large scale" is not defined and is a qualitative or relative term. Where is the boundary between large and small?

The following will probably be excluded:

- Railway network signalling
- Traffic lights and other road equipment
- Alarm systems and HVAC in large factories and large office buildings
- Wiring, switches, sockets, circuit breakers fuses, etc. but only where they are used in large-scale fixed installations

An issue here is that the same components are used in for example, alarm systems or HVAC in large buildings and in small buildings, the former being excluded but not the latter. This issue needs to be resolved

- **Equipment specifically designed solely for R&D**

This would exclude development boards. Cables will be in scope whereas consumables continue to be excluded. Also excluded, as at present is any equipment designed to be used as integral parts of any products such as those listed above, that are excluded from scope. Vehicles and batteries also excluded from RoHS because they are covered by the ELV and batteries directives.

There are ongoing concerns over the status of 'dev kits', in particular low cost, open PCB evaluation kits. Previous enforcement guidelines specified that R&D equipment would be in scope if they transfer data (falling into category 3). However, after prolonged protest from manufacturers the recast now states that equipment will be out of scope if used solely for R&D purposes. So whilst a PCB kit will be out of scope, a programmer in an enclosure for production quantities will be in scope. However, there is a good chance that R&D will again fall into scope with the 2019 open scope.

Use of pre-RoHS parts

A new exclusion has been agreed that would allow manufacturers of new equipment to use parts from old equipment that had been placed on the market before 1 July 2006. This exclusion will apply only until 1 July 2016 and so will be of little benefit to those products in categories 8, 9 and 11.

Additional substance restrictions

After protracted negotiations, it was eventually agreed that there should be no additional substances restricted by RoHS but the Commission will carry out reviews of substances for possible restriction using a procedure based on the restriction process used for the REACH regulation. Four hazardous substances (BBP, DBP, DEHP & HBCDD) were identified for priority assessment and possible future ban. It seems very likely that some more substances will be added to the list of restrictions but these should be those which are proven to have an unacceptable risk to health or the environment and safer alternatives exist.

Industry will face a significant compliance data collection exercise as it did leading up to 2006. Gathering compliance information was certainly a challenge before and this will become more complex, with potential new product categories falling within scope, as well as changes to exemptions.

Spare parts

Permission to use non-compliant spare parts was extended to equipment benefitting from an exemption that applied when the product was originally placed on the market.

Exemptions

A new annex VI has exemptions specific to the new product categories 8 and 9 (medical devices and monitoring and control instruments) and has been included whereas the existing exemptions Annex (now III) applies to all products that are in scope.

Exemption expiry process

The 4-year review has been replaced by automatic expiry of all exemptions unless they are renewed. The automatic expiry period has a maximum of five years for categories 1 – 7 and 10 (exemptions in Annex III) and up to seven years for categories 8, 9 and 11 (Annex VI). Applications for exemption renewal must be made at least 18 months before expiry to guarantee a decision from the Commission, which should be made at least six months before expiry. Short transition periods may be granted where request for renewal are turned down. New exemption criteria were introduced covering the availability and reliability of substitutes and socio-economic impacts will be taken into account.

The Commission had a mandate to establish detailed rules for exemption requests to establish legal certainty for economic operators pending a Commission decision on a renewal request.

Who is responsible and how to comply

CE marking

RoHS will become a CE mark directive. CE marking and associated obligations will begin as soon as the recast RoHS enters force for products currently in scope. It will also be required for those products that are currently excluded at the time when these are included in scope. This will mean that equipment manufacturers in EU and importers of equipment into EU will be required to CE mark finished products (but not components cables) that are included in the scope of RoHS.

The following will be required:

- CE mark equipment and cables sold separately
- Declarations of conformity will need to list any harmonised standards (once these are written) used to show compliance.
- Technical files will also be required and be kept for 10 years.

This new requirement will affect manufacturers, importers and distributors.

Articles 7-17 of the recast directive impose the new product conformity assessment requirements and market surveillance mechanisms in line with the "Marketing of products" Regulations (Commission decision 768/2008/EC on a common framework for the marketing of products). Articles 7 -10 list the specific obligations of manufacturers, authorised representatives, importers and distributors. This change to RoHS will mean that all of the supply chain in the EU has legal responsibility for compliance.

Demonstration of compliance

RoHS will become a CE marking Directive applying to finished goods, with some typical implications shown below. Manufacturers, importers and distributors will be responsible for some, or all of these activities:

- Verify that products are CE marked and supplied with the required documentation.
- Audit manufacturers to ensure that they have, where appropriate, carried out sample testing.
- Audit importers and manufacturers located in the EU to ensure they keep registers of complaints, details of non-conforming equipment and product recalls.
- Audits should be on a sample basis although new products could be checked upon receipt.
- Check products to ensure they are correctly labelled.
- Ensure that manufacturers label their equipment with the type, batch or serial number of the product. This may be placed on the packaging if there is insufficient space on the product. EU manufacturers are also obliged to label products with their name and address.
- Where products are manufactured outside the EU it is the importer who has to label with their name, or registered trademark, and address. However, where the distributor is the importer, thorough conformity assessment procedures will be required as the importer is legally responsible for ensuring compliance.
- Distributors need to ensure that product compliance is not jeopardised while under their control. This should be no issue where the equipment stays in its box.
- Distributors need to assess the compliance status of products they sell and not rely purely on declarations from suppliers. This implies that a sample testing process is required (obligated if the distributor is the importer). Corrective action must be taken to bring products into conformity if they suspect that they do not comply, or withdraw the product from sale.
- Distributors must inform the relevant national enforcement authorities if any non-compliant equipment "presents a risk". A risk assessment should be carried out and documented.
- Distributors will need to build "technical files" that include documentation such as supplier declarations of compliance, any data supplied by the manufacturer or importer, results of any distributor assessment etc, and keep for 10 years. This implies that obsolete or discontinued equipment, and the associated technical files, should not be removed from websites.
- Where distributors import equipment under their own name they are required to draw up technical documentation as specified in regulation 768/2008/EC**. Where the product complies affix a CE mark, provide a declaration of conformity, affix labels with name and address and keep all documentation for 10 years.

In summary, good record keeping will be essential as most of these obligations are to produce documentation that can be assessed by enforcement bodies.

****Regulation 768/2008/EC defines what manufacturers, importers and distributors need to do to demonstrate compliance with CE mark directives such as EMC, LVD and RoHS in the future. It describes conformity assessment procedures such as what should be included in technical files and declarations of conformity.**

Please note:

The information contained in this guide is of a general nature and is not intended to address the circumstances of any particular individual or entity. Although we endeavour to provide accurate and timely information, there can be no guarantee that such information is accurate as of the date it is received or that it will continue to be accurate in the future. No one should act on such information without appropriate professional advice after a thorough examination of the particular situation.

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