



National
Measurement
Office

Guidance to RoHS Directive 2011/65/EU



Contents

About this guidance	3
RoHS 2 frequently asked questions	5
Guidance for manufacturers	9
Ensuring that your test report is valid	11
Making an EU declaration of conformity (DoC)	13
CE marking your product	14
Guidance for authorised representatives	15
Guidance for importers	16
Guidance for distributors	18
Due diligence	19
Table of obligations	20
Decision tree	21
Glossary	22
Appendix 1	
Exemptions: medical devices and monitoring and control instruments	24
Appendix 2	
Exemptions: other applications	25

National Measurement Office: market surveillance authority

About this guidance

New regulations came into effect on 2 January 2013 restricting the amount of hazardous substances that can be used in electrical and electronic equipment and extending those restrictions to new categories of equipment.

This guidance is designed to help UK businesses to comply with the regulations. It will help you to understand the new rules and how they differ from existing legislation, and your obligations as a business, whether you are a manufacturer or authorised representative, an importer or a distributor.

Why 'RoHS 2'?

EU Directive 2011/65/EU (Restriction of the Use of Certain Hazardous Substances in Electronic and Electrical Equipment) aims to prevent hazardous substances from entering the production process and thereby keep them out of the waste stream. The regulations are known as RoHS 2 because they replace earlier RoHS regulations that came into force in 2002.

As well as extending the restrictions to new categories of equipment, the regulations help to harmonise similar legislation across the European Union (EU) and ensure a simpler, more effective regime overall. This will help UK businesses by enabling fair markets, thereby generating greater market access.

What is changing?

RoHS 2 introduces CE marking for electrical and electronic equipment for the first time. It also requires manufacturers to prepare an EU declaration of conformity (DoC) demonstrating that they have complied with all their legal obligations.

Over the next few years, the regulations will extend restrictions on the use of hazardous substances across a wider range of products and devices, including:

- medical devices and monitoring and control instruments
- *in vitro* medical devices
- monitoring and control instruments
- industrial monitoring and control instruments.

From July 2019, RoHS 2 will apply to all electrical and electronic goods regardless of their type, design or purpose.

What this means for your business

Manufacturers, authorised representatives, importers and distributors of the products listed above will need to comply with RoHS regulations over time as the regulations extend to their products. Businesses that are already covered by the rules will, in general, continue to comply with RoHS 2 in the same way as RoHS 1. However, there are some new processes and documentation requirements that they need to follow. All types of businesses, except distributors, will have to keep relevant compliance documentation for a minimum of 10 years.

Our role as market surveillance authority

The National Measurement Office (NMO) is an executive agency of the Department for Business, Innovation & Skills (BIS) and is the appointed market surveillance authority responsible for ensuring compliance with the RoHS regulations within the UK. We work in cooperation with businesses to help ensure that the

About this guidance *continued*

regulations are implemented effectively, which involves:

- providing support and guidance
- product testing
- monitoring compliance
- carrying out inspections
- taking enforcement actions where necessary.

Our enforcement actions are always proportionate, appropriate and designed to help businesses achieve long-term compliance, thereby benefiting UK trade and promoting economic growth.

The European Commission (EC) has committed to reviewing the RoHS 2 regulations periodically, starting in 2014. We will also review this guidance and keep it updated whenever the rules change and to reflect changes in the interpretation of the regulations.

Ask our online advice service

If you have a question about the new regulations or need help or advice on how to comply with them, you can ask our enforcement team. Just go to www.bis.gov.uk/nmo/enforcement/enquiries and send us your query and we will get back to you with an answer within a few days.

If you want to consult the legislation, you can read the full text of the RoHS 2 Directive on our website. There is useful information on the regulations at http://ec.europa.eu/environment/waste/rohs_eee/events_rohs3_en.htm and in the BIS guidance notes at www.bis.gov.uk/assets/biscore/business-sectors/docs/r/12-1167-restriction-of-hazardous-substances-regulations-guidance.pdf

RoHS 2 frequently asked questions

EU Directive 2011/65/EU (Restriction of the Use of Certain Hazardous Substances in Electronic and Electrical Equipment) restricts the amount of hazardous substances that can be used in the manufacture of electrical and electronic equipment (EEE).

Such hazardous substances can be difficult to manage at the end of the product life cycle, when electrical and electronic products are being disposed of or recycled. Therefore, the regulations focus on restricting them at the beginning of the cycle – during production – in order to keep them out of the waste stream.

The new regulations, known as RoHS 2, came into effect on 2 January 2013, replacing the previous regulations (RoHS 1) that were introduced a decade ago.

How is RoHS 2 different from RoHS 1?

RoHS 2 continues the restrictions introduced in RoHS 1, but will extend them to more products, including medical devices and monitoring and control equipment, over the next few years, and to all EEE not specifically exempted by 2019.

The regulations also introduce CE marking for EEE for the first time, and require manufacturers to prepare a declaration of conformity demonstrating compliance with all their legal obligations. Meanwhile, importers and authorised representatives must also maintain a document trail demonstrating compliance.

What is EEE?

EEE is defined as any equipment with a voltage rating not exceeding 1,000V for AC and 1,500V for DC that requires electric currents or electromagnetic fields to work, or equipment used for the generation, transfer and measurement of electric currents and fields. EEE can be a component or assembly used in a finished product. Cables and spare parts for repairing, reusing, updating or upgrading a product are all EEE. The RoHS 2 regulations apply to EEE in specific product categories; see 'Which EEE is affected?' and 'Which EEE is exempted?' overleaf.

Which substances are restricted?

RoHS 2 bans anyone from placing on the EU market EEE in which any homogenous material contains more than the tolerated maximum concentration values (MCVs) of six substances:

- lead (Pb)
- mercury (Hg)
- hexavalent chromium (Cr6)
- cadmium (Cd)
- polybrominated biphenyls (PBB)
- polybrominated diphenyl ether (PBDE).

What is a 'homogenous material?'

A homogenous material is any material that has a uniform composition throughout, or any component of the finished product that cannot be removed or detached by any action such as unscrewing or cutting. This can be anything from the speakers in a radio to the outer casing of its cables.

The tolerated MCV for each restricted substance is 0.1%, or 1,000 parts per million (PPM), except for cadmium which has a limit of 0.01% or 100 PPM. The limits apply to each homogenous material, so if any one contains more than the allowed concentration, the whole product fails to comply.

Have the restricted substances changed?

No. The listed substances are the same ones that are restricted under RoHS 1. However, the Directive commits the European Commission (EC) to reconsidering this list, with its first review to be completed by July 2014 and regular reviews after that. These reviews will look at how RoHS 2 can be harmonised with other regulations on chemical use, such as Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), 1907/2006/EC, in order to simplify the overall regulatory regime.

Which EEE is affected?

Restrictions on the use of hazardous substances already apply to these product categories:

- large household appliances
- small household appliances
- IT and telecommunications equipment
- consumer equipment
- lighting equipment (including electric lightbulbs and household luminaries)
- electrical and electronic tools (with the exception of large-scale stationary industrial tools)
- toys, leisure and sports equipment
- automatic dispensers.

RoHS 2 will extend the restrictions over the next few years to include:

- medical devices and monitoring and control instruments from **July 2014**
- *in vitro* medical devices from **July 2016**
- monitoring and control instruments from **July 2014**
- industrial monitoring and control instruments from **July 2017**
- all EEE not specifically exempted (see below) from **July 2019**.

Which EEE is exempted?

Some categories of EEE are exempt from restrictions on the use of hazardous substances, for example where they are required for important national purposes. These include:

- equipment built specifically for military purposes or which is essential for national security

- equipment designed to be sent into space
- transport for people or goods
- active medical implants
- photovoltaic panels (for public, commercial, industrial or residential use)
- equipment specifically designed for research and development (for professional use)
- non-road mobile machinery for professional use that has an onboard motor
- large-scale stationary industrial tools
- large-scale fixed installations
- equipment specifically designed to be part of another type of equipment that is exempted.

There are also exemptions that allow hazardous substances to be used above the tolerated MCV levels for certain specific technical applications. You can find a full list of the specific exemptions that were in force before RoHS 2 in Appendix 2 on page 25. There is a full list of the exemptions from the newly restricted product categories introduced by RoHS 2 in Appendix 1 on page 24.

RoHS 2 commits the EC to reviewing the exemptions regularly in order to see whether new exclusions need to be added. Manufacturers can apply for new specific exemptions at any time. However, the process for doing this has changed; see annex V of the directive for more information.

Read more about exemptions on our website at www.bis.gov.uk/nmo/enforcement/rohs-home/rohs-exemptions

What is 'placing on the market'?

RoHS 2 makes it an offence to place non-compliant EEE on the EU market. 'Placing on the market' happens when a product that has completed its manufacturing stage is made available for distribution and sale for the first time in the EU. It applies to individual products regardless of whether they are part of a wider product line or series. If EEE is placed on the market in another EU country, and subsequently imported to the UK, the UK importer must ensure that the products are compliant.

How does RoHS affect me?

RoHS 2 places legal obligations on you if you make or trade in EEE in any restricted product category as a:

- **manufacturer**
- **manufacturer's authorised representative**
- **importer**
- **distributor** (including retailers).

For example, manufacturers must ensure that EEE are CE marked and must prepare a declaration of conformity confirming that they have complied with the regulations. If you are involved in more than one of these roles, you will be responsible for complying with the obligations of each activity; for example, if you import or distribute EEE in the UK under your own brand, you are considered to be the manufacturer of those products and must comply with the obligations of a manufacturer.

RoHS 2 frequently asked questions *continued*

To find out which obligations apply to you, turn to the relevant guidance pages for your activity.

How will RoHS 2 be enforced?

The NMO is the appointed market surveillance authority responsible for ensuring compliance with the RoHS regulations as set out in Statutory Instrument 2012 No: 3032; see www.legislation.gov.uk/uksi/2012/3032/pdfs/uksi_20123032_en.pdf

We are committed to working with businesses in a proportionate, appropriate way to help them to comply with the regulations. We will only take enforcement action where all other efforts have failed to achieve compliance.

However, where enforcement is necessary, the regulations give the NMO a range of powers, including:

- the power to make test purchases
- powers of entry
- warrants
- the power to inspect, seize and detain EEE
- the power to request technical documentation and other evidence
- a range of sanctions, including fines of up to £5,000 per non compliant product.

What happens when?

Date	Obligation
2 January 2013	Manufacturers must CE mark EEE (see page 14) and prepare a declaration of conformity (see page 13) confirming that they have met their legal requirements
2 January 2013	Distributor obligations apply (see page 18)
22 July 2014	Restrictions are extended to medical devices
22 July 2014	Restrictions are extended to non-industrial monitoring and control instruments
22 July 2016	Restrictions are extended to <i>in vitro</i> medical devices
22 July 2017	Restrictions are extended to industrial monitoring and control instruments
23 July 2019	Restrictions are extended to all EEE not specifically exempted

Guidance for manufacturers

The manufacturer of a product is responsible for ensuring that it complies with the RoHS 2 regulations restricting the use of certain hazardous substances in electrical and electronic equipment (EEE).

See Appendices 1 and 2 for a list of the restricted substances and the product categories of EEE to which the restrictions apply.

Who is a manufacturer?

You are considered to be the manufacturer of EEE if you manufactured it or if you market it under your name or trademark – even if it was designed or manufactured by someone else. So, wherever products have been re-branded, the brand owner is the manufacturer for the purposes of RoHS 2.

Manufacturers can be based outside the EU. If they are, they can delegate some administrative responsibilities to an authorised representative within the EU but cannot delegate their obligations to ensure compliance, such as setting up production control systems or drawing up technical documentation.

Sub-contractors

The manufacturer is responsible for ensuring the compliance of the whole product, including any ready-made components or finished products that may be used in its assembly. Therefore, sub-contractors are not manufacturers under RoHS 2. The manufacturer must retain control over any sub-contracted part of the production process and ensure that the sub-contractors

provide all of the information necessary to demonstrate compliance.

Manufacturers' obligations

When you place EEE on the EU market for the first time, you must do the following:

- ensure that the design and manufacture of your product complies with RoHS 2; this includes each **homogenous material** within the EEE (see page 6)
- set up effective production control systems to support compliance and review them to ensure that the EEE remains compliant over time
- draw up **technical documentation** demonstrating compliance (see page 10)
- complete an assessment of conformity with the regulations
- prepare a **declaration of conformity** (see page 13)
- keep all technical documents and the declaration of conformity for 10 years
- fix the **CE mark** to the finished product
- clearly mark the EEE with type, batch or serial number for identification
- place your name, trade name or trademark on the product and packaging
- keep a register of recalled products and inform members of your supply chain of these
- ensure that any non-compliant EEE is withdrawn from the market, and take corrective action to make it comply with the regulations
- inform the NMO of the action you are taking to ensure compliance
- provide documentation and any other information required by the NMO to demonstrate compliance.

Guidance for manufacturers *continued*

Helpful steps to ensure production control

To comply with RoHS 2, you need to demonstrate that you have effective production controls in place. The following are not legal requirements, but will help you to comply with the regulations,

- Appoint a designated compliance officer who is responsible for managing compliance issues and has the authority to take action if compliance systems fail.
- Have good systems for collecting compliance information and documents and review these regularly.
- Make sure that your product testing is adequate to reflect the scale of production and the complexity of the product.
- Consider whether all reasonable steps have been taken to ensure the production process complies with the regulations.

Preparing technical documentation

Manufacturers are responsible for compiling technical documentation, known as the 'technical file', to demonstrate compliance with the regulations. This should include information on the design, manufacture and operation of the EEE, which together make it possible to assess whether the product meets RoHS 2 requirements. The file should include:

- a general description of the product and how it operates
- conceptual, design and manufacturing drawings, and schemes of components, subassemblies and circuits, with descriptions and explanations

- a list of harmonised standards (see below) and/or other relevant technical specifications used
- results of design calculations and examinations
- **test reports** (see page 11).

This documentation must be held by the manufacturer for a period of 10 years after the product has been placed on the market.

Using harmonised standards

A recognised European Standards Organisation may be able to provide you with an approved European Standard to help you demonstrate compliance with these obligations. This is a template for assessing EEE and providing the required technical information and documentation. If you choose not to use a harmonised standard, you must be able to prove that you have met the technical requirements of the regulations. EN 50581:2012 is the relevant harmonised standard that is applicable to requirements for documentation for conformity with RoHS 2.

Presumption of conformity

Manufacturers who assess their EEE using a European Standard published in the *Official Journal of the European Union* are presumed to have complied with the regulations. Although this has a cost attached, it may save you employing an external assessor to carry out a compliance assessment, and may therefore be a cost-effective solution.

Ensuring that your test report is valid

As part of their obligation to supply technical documentation, manufacturers must include a test report from a laboratory that demonstrates compliance with RoHS 2.

What is a test report?

All EEE should undergo testing in a laboratory at some point during or after the production process. The test report that the laboratory provides you with can be important in demonstrating that your product complies with the regulations. However, it is your responsibility as manufacturer to ensure that your test report is prepared correctly and accurately reflects the composition of all the components and materials used.

What to consider before accepting a test report

In order to demonstrate compliance with RoHS 2, a test report must be up to date and clearly show that the product contains less than the maximum level of hazardous substances, including detailed information about each material or component supplied to you before assembly. Here are some questions you should ask to assess whether a test report demonstrates compliance:

- **Is the report up to date?** Have there been any changes to the production process since the report was prepared? Have any of the components been modified? Have you changed suppliers? If the answer to any of these is yes, then your test report is unlikely to still be valid. You should check that your test report is up to date and refers only to the actual components in the finished product.
- **Does the report clearly show compliance?** The report should clearly show that each homogenous material (see below) used in the product contains less than the maximum concentration value (MCV) of each hazardous substance. Use the [table of MCVs](#) overleaf to check against your test report.
- **What method was used to prepare the report?** The methodology used in testing for hazardous substances must be clearly listed in the report. You should be familiar with testing methods and question suppliers if you are unsure how their component was tested.
- **Is the report in English?** Your compliance information needs to be clearly understood and your test report should be in English or translated into English. If you need to supply a test report in any other country, it should be supplied in the language commonly spoken in that country.

Testing homogenous materials

You need to be careful in preparing test samples of each individual [homogenous material](#) within your EEE. If you break down or grind the material to fit a sample size, the hazardous substance contained in the material may be diluted and the test result may not be valid. Speak to your laboratory about this before sending any test samples.

Choosing a laboratory

The laboratory you use should be trustworthy and your test report should be signed by someone who is authorised to do so. To ensure compliance, you should consider using an accredited laboratory

Ensuring that your test report is valid *continued*

such as UKAS in the UK or another internationally recognised accreditation service – preferably a signatory to the International Laboratory Accreditation Cooperation (ILAC).

You should also review any documents provided by a supplier in support of their declaration to ensure that they are accurate and that they demonstrate the facts they are intended to prove.

Suppliers' declarations and supporting information

Your suppliers may provide you with declarations of compliance for their components, materials or assemblies. These can be useful in demonstrating compliance – especially if you have had a strong relationship with the supplier over a sustained period and understand their processes. However, it is your responsibility to ensure that any declaration is valid. Here are some questions to ask:

- Is the declaration too generic? To be valid, it needs to refer specifically to the goods supplied.
- Are there any caveats? Wording such as 'to the best of my knowledge' and 'no intentional use' may devalue a supplier's declaration.
- Who signed it? You need to be sure that the declaration was signed by a person who is authorised to do so.

Test report checklist

- ✓ Choose an accredited laboratory if possible.
- ✓ Make sure that your report is up to date and refers only to materials actually contained in the finished product.
- ✓ Check that the report clearly shows that each homogenous material contains less than the MCV for each hazardous substance.
- ✓ Be careful when preparing test samples that you do not dilute the hazardous substance content, as this will make those samples invalid.
- ✓ Make sure that the method of testing is clearly stated.
- ✓ Check any declarations of compliance from your suppliers to ensure that they are accurate and that supporting documents are relevant to demonstrating compliance.
- ✓ Submit your report in English.

Maximum concentration values of hazardous substances

Restricted hazardous substances		Restricted limit (%)	Restricted limit (ppm)
Lead	Pb	0.1	1,000
Mercury	Hg	0.1	1,000
Hexavalent chromium	Cr6	0.1	1,000
Cadmium	Cd	0.01	100
Polybrominated biphenyls	PBB	0.1	1,000
Polybrominated diphenyl ethers	PBDE	0.1	1,000

Making an EU declaration of conformity

Once you have tested the EEE, completed the technical file and carried out an assessment of conformity with the regulations, you must prepare a declaration of conformity (DoC).

This is a self-declaration that the EEE meets all of the RoHS 2 requirements that apply to that product. By making the declaration, you assume all responsibility for compliance with the regulations.

The DoC must include your business name and address and information to identify

the product, such as the brand and serial number. The declaration must be signed by you or by one of your employees.

If there are several sets of regulations on hazardous substances that apply to your product – for example RoHS 2 and the REACH regulations – you can declare compliance with all of them in a single DoC. You must provide the DoC upon request, translated into the local language, to the market surveillance authority in any EU country where your product is sold.

How to structure your declaration of conformity

1. The unique identification number of your EEE.
2. Your business name and address or that of your authorised representative.
3. A statement that the DoC is issued under your sole responsibility.
4. Information such as the serial number, to identify your EEE and ensure that it is traceable.
5. A statement that your EEE complies with the RoHS 2 requirements that apply to it.
6. References for the relevant harmonised standards or technical specifications you used, if applicable.
7. Additional information.
8. Place and date of issue.
9. Name, function and signature.

CE marking your product

The RoHS 2 regulations require that all new EEE placed on the EU market must carry the CE mark. This is part of the self-certification process and is designed to be a visible demonstration of conformity.

The CE mark indicates compliance not only with RoHS 2 but with all EU legislation. By affixing the CE mark, you take full responsibility for compliance with all EU regulations that apply to your product. The general principles of CE marking are outlined in Regulation (EC) 765/2008, at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:EN:PDF>

As RoHS 2 restrictions are extended to [new product categories](#), such as medical devices, from 2014 onwards, these products will need to be CE marked from the date from which the restrictions apply.

The CE mark does not indicate that the product is made in the EU, only that the product meets the requirements of EU legislation.

Applying the CE mark

You must fix the CE mark to your product before it is placed on the market. Follow these rules to apply the CE mark successfully:

- The CE marking must not be smaller than 5mm. If you change its dimensions, you must do so proportionally, so that it retains the same relative shape and size.
- The CE marking should be visible and

legible. It should be indelibly fixed to the finished EEE or to its data plate – this means that it must be lasting, enduring and not easily removed.

- Where the CE mark cannot be fixed indelibly to the product because of the nature of the EEE, it should be fixed to the packaging and the accompanying documents.

EU Member States are required to ensure correct application of CE marking and take appropriate action if the mark is incorrectly used. The penalties may include criminal sanctions for serious infringements. Inaccurate use of CE marking is regarded as an offence under the RoHS 2 Directive.

Guidance for authorised representatives

Do you also import or distribute electrical and electronic equipment in the UK?

If your answer is yes, you will also need to comply with the obligations for [importers](#) and/or [distributors](#) (see pages 16–18).

An authorised representative is anyone who has received a written mandate from a manufacturer based within or outside the EU to carry out certain tasks involved in placing electrical and electronic equipment (EEE) on the EU market.

These tasks are strictly administrative; for example, keeping the technical documents necessary to demonstrate compliance. The manufacturer cannot delegate any tasks to you that are necessary to ensure compliance, such as drawing up technical documents or checking production-control systems.

The written mandate must clearly specify the nature of the delegated task and the limits of your authority as an authorised representative. If it is requested, you must be able to produce this mandate.

Who can be an authorised representative?

To be an authorised representative, you must be established within the EU. You can be a sub-contractor, agent, importer or distributor. If you import or distribute EEE that is being placed on the market, you will also need to comply with the RoHS 2 obligations that apply to those roles.

Authorised representatives' obligations

As a manufacturer's authorised representative, you must:

- keep the file of technical documentation and the declaration of conformity for 10 years after the EEE has been placed on the market
- comply with any requests for information from the NMO
- cooperate with the NMO in any action it requires to ensure that the EEE complies with the regulations.

Guidance for importers

Do you market electrical and electronic equipment under your own brand?

If your answer is yes, you will also need to comply with the [manufacturers' obligations](#) (see page 9).

Anyone who imports electrical or electronic equipment (EEE) into the EU and places them on the EU market must be able to show that that EEE complies with the requirements of the RoHS 2 regulations.

This includes being able to provide technical documentation demonstrating compliance, together with the manufacturer's declaration of conformity (DoC). The importer must have an assurance from the manufacturer that these documents will be available if required.

If you have also been appointed as authorised representative to carry out administrative tasks on behalf of the manufacturer, you must have a written mandate specifying this role (see '[Guidance for authorised representatives](#)' on page 15).

If imports do not comply

If you have reason to believe that the EEE does not comply with the regulations, you must not place it on the EU market until it is compliant. If the EEE has already been placed on the market, you must take the corrective measures necessary to bring it into conformity, recalling or withdrawing the product and not allowing it onto the market again until it is compliant. In both cases, you must immediately inform the NMO and the manufacturer.

When is an importer considered to be a manufacturer?

- If you import EEE that you market under your own brand, you are considered to be the manufacturer of those products.
- If a product is exempted from the RoHS restrictions but you then make it available on the market for a different purpose, you have modified the product and are also considered to be the manufacturer.
- In both of these cases, you must comply with all of the [RoHS 2 obligations for manufacturers](#).

Importers' obligations

As an importer of EEE into the EU, you must:

- only place on the market EEE that complies with the RoHS 2 regulations
- be sure that the manufacturer has carried out essential compliance tasks, including the conformity assessment, providing technical documentation, preparing a DoC and affixing the CE mark as well as the type, batch or serial number for product identification (see '[Guidance for manufacturers](#)' on page 9)
- indicate your own trade name or trademark and address on the EEE or packaging
- not place an EEE on the market if you believe that it may be non-compliant
- recall all non-compliant EEE that has already been placed on the market
- inform the NMO and the manufacturer of any non-compliance and take immediate action to ensure that that EEE becomes compliant before placing it on the market
- keep a register of recalled and non-compliant EEE and copy this to distributors
- keep the technical documentation and the DoC available for 10 years after the EEE has been placed on the market
- comply with NMO requests for information to demonstrate compliance.

Guidance for distributors

Do you market electrical and electronic equipment under your own brand?

If your answer is yes, you will also need to comply with [manufacturers' obligations](#) (see page 9).

Distributors of electrical and electronic equipment (EEE) must take due care not to make any products available to the market that do not comply with the RoHS 2 regulations.

As a distributor, you do not have to ensure compliance or keep any compliance documentation, but you must take reasonable steps to be sure that the manufacturer or importer has complied with the regulations.

Who is a distributor?

A distributor is anyone who is not a manufacturer or importer and who makes EEE available on the market. This includes wholesalers and all retailers of electrical products.

If you are also acting as an [authorised representative](#) or an [importer](#), you must comply with the RoHS 2 obligations that apply to the relevant role. If you market EEE under your own brand, you are considered to be the manufacturer of those products and must comply with the [obligations for manufacturers](#).

When is a distributor considered to be a manufacturer?

- If you distribute EEE under your own brand, you are considered to be the manufacturer of those products.
- If a product is exempted from the RoHS restrictions but you then make it available on the market for a different purpose, you have modified the product and are also considered to be the manufacturer.
- In both of these cases, you must comply with all of the [RoHS 2 obligations for manufacturers](#).

Distributors' obligations

As a distributor of EEE, you must:

- verify that the CE mark has been affixed, as well as the type, batch or serial number for product identification, and that technical documentation required to demonstrate compliance is available
- verify that the manufacturer's trade name or trademark and address is on the EEE or packaging, as well as the importer's trade name and address if applicable
- not place an EEE on the market if you believe that it may be non-compliant
- remove any non-compliant EEE that has already been placed on the market
- inform the NMO and the manufacturer or importer of any non-compliance
- ensure that non-compliant EEE is not returned to the market until it complies with the regulations
- comply with NMO requests for information to demonstrate compliance.

Due diligence

As a manufacturer, importer or distributor of EEE, you should be able to show that you took all reasonable precautions, steps and measures to ensure compliance. This is known as 'due diligence'.

To demonstrate due diligence, a manufacturer should be able to show that they have introduced a series of appropriate and effective processes to check production control and material supply and have made sure that those checks were being carried out. If you have set up a system but it is not being implemented, then you will not have completed due diligence.

Your systems should also take account of all business activities that may impact on compliance. For example:

- the reliability of your suppliers and the selection of your raw materials and components
- how you manage goods in control and quarantine
- your production processes and whether they are vulnerable to contamination
- the evidence and documentation you collect to support your processes
- stores control (mixing compliant and non-compliant materials/components)
- staff training and experience.

Document, operate and review

You should be able to document your control systems, operate them effectively and review them regularly. You should make sure that employees are aware of all established control systems and trained as appropriate. You should also consider auditing your systems to ensure that they remain fit for purpose and any identified failures are resolved at the earliest opportunity.

Creating a system of checks throughout the supply chain can be a complex task. The NMO enforcement team tries to help businesses wherever possible and, in doing so, increase levels of compliance in the UK.

You will find detailed advice based on the best and most up-to-date information available, at www.bis.gov.uk/nmo/enforcement/rohs-home/due-diligence

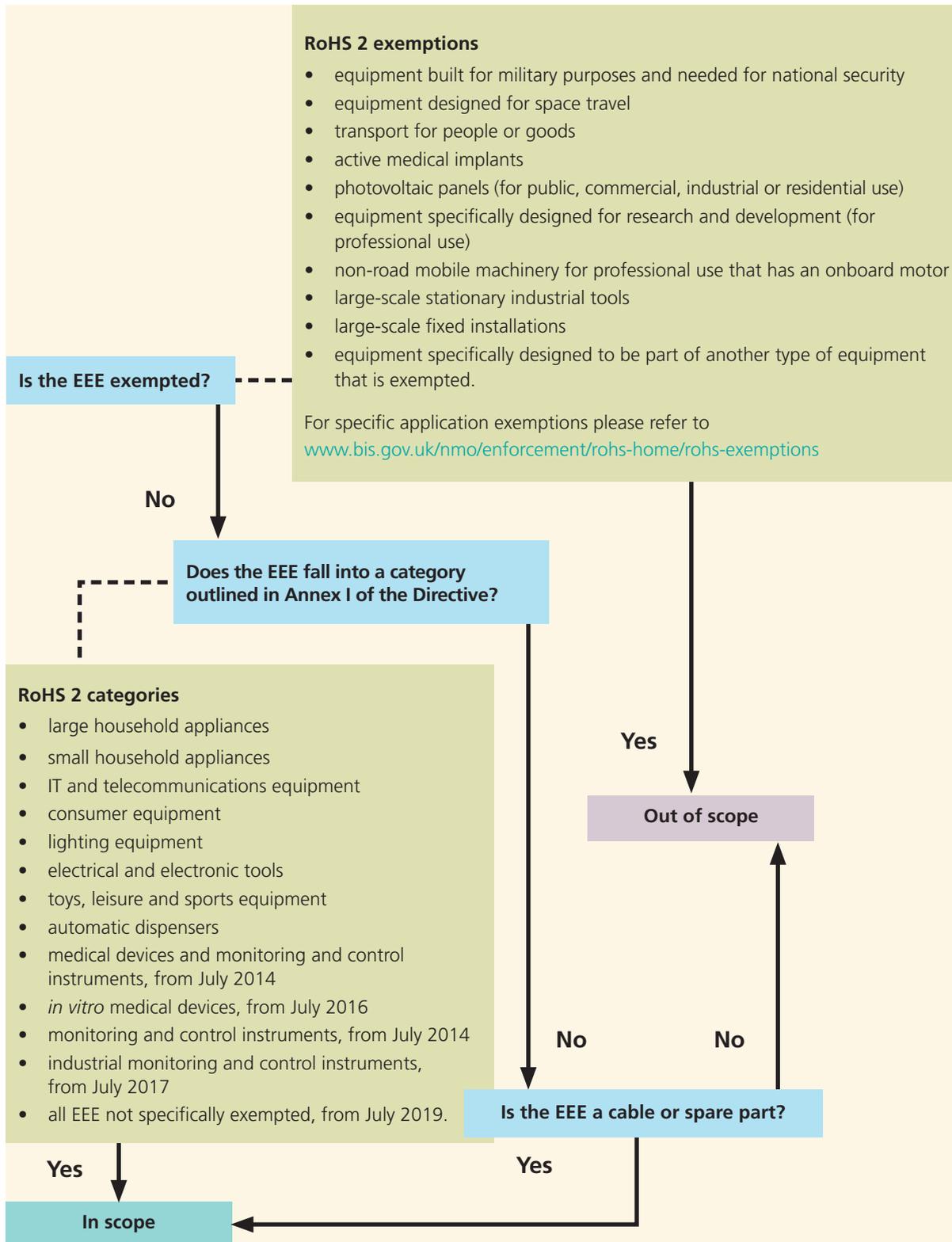
Table of obligations

This table summarises the obligations of all economic operators that are affected by RoHS 2.

Legal obligations	Manufacturer	Authorised representative	Importer	Distributor
Design and manufacture electrical and electronic equipment (EEE) in compliance with RoHS 2	✓			
Place only compliant EEE on the EU market	✓		✓	✓
Draw up technical documentation	✓			
Implement production control systems and checks to ensure compliance	✓			
Draw up an EU declaration of conformity	✓			
Affix CE mark	✓			
Ensure that the required technical documentation, in addition to the declaration of conformity, is available on request			✓	✓
Ensure that technical documentation, in addition to the declaration of conformity, remains available for 10 years after the EEE is placed on the market	✓	✓	✓	
Ensure that the EEE has been CE marked by the manufacturer			✓	✓
Keep a register of all non-compliant and/or recalled EEE	✓		✓	
Ensure that the manufacturer keeps a register of all non-compliant and/or recalled EEE			✓	
Ensure that the manufacturer has carried out an appropriate assessment of conformity			✓	
Ensure that the manufacturer has drawn up technical documentation			✓	
Ensure that the EEE remains compliant for as long as it is produced	✓			
Ensure that the EEE is marked with type/serial/batch number for identification	✓		✓	✓
Ensure that the EEE is marked with the manufacturer's trademark/trade name and address	✓			✓
Ensure that the EEE is marked with the importer's trade name and address			✓	✓
Take corrective measures to ensure that any non-compliant EEE becomes compliant	✓		✓	✓
If requested, provide the NMO with all the information required to demonstrate conformity	✓	✓	✓	✓
Cooperate with the NMO and take any action it requests to ensure conformity	✓	✓	✓	✓
Meet all manufacturer obligations if you market EEE under your own trademark/trade name			✓	✓

Decision tree

This will help you to decide whether your electrical and electronic equipment (EEE) is affected by RoHS 2.



Glossary

Active implantable medical device	Any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.
Authorised representative	Anyone who has a written mandate from a manufacturer to carry out specified administrative tasks on their behalf when placing EEE on the market.
CE marking	European conformity marking by a manufacturer indicating that the product complies with all EU regulations, including RoHS 2.
Conformity assessment	An assessment carried out to test whether the EEE production process meets the requirements of the regulations.
Conformity assessment body	Body that performs conformity assessment activities, including calibration, certification, inspection and testing.
Declaration of conformity (DoC)	A document in which the manufacturer declares that its product meets all of the requirements that apply to it.
Directive	A legislative act of the EU that requires Member States to achieve a particular result without dictating the means of achieving that result.
Distributor	Any person in the supply chain, other than the manufacturer or importer, who makes EEE available on the market.
Economic operators	Manufacturers, authorised representatives, importers and distributors.
Electrical and electronic equipment (EEE)	Any electrical or electronic product with a voltage rating below 1,000V for AC and 1,500V for DC that requires electric currents or electromagnetic fields to work, or equipment used for the generation, transfer and measurement of electric currents and fields.
Enforcement authority/market surveillance authority	The regulatory body appointed in each EU country to enforce the regulations. In the UK, this is the National Measurement Office (NMO).
Harmonised standard	EU standardised procedure for providing technical information needed for compliance. Using a harmonised standard confers a presumption of conformity.
Homogenous material	A homogenous material is any material that has a uniform composition throughout, or any component of the finished product that cannot be removed or detached by any action such as unscrewing or cutting.
Importer	Anyone who imports EEE from outside the EU and places it on the EU market.
Industrial monitoring and control instruments	Monitoring and control instruments used in industrial installations that are designed exclusively for industrial professional use.

In vitro medical device	Any medical device intended by the manufacturer to be used for the examination of specimens, including blood and tissue donations, derived from the human body. Specimen receptacles are considered to be <i>in vitro</i> diagnostic medical devices. General laboratory equipment does not count as an <i>in vitro</i> medical device unless intended by the manufacturer to be used in this way.
Large-scale fixed installation	A large-scale combination of several types of apparatus and, where applicable, other devices, which are assembled and installed by professionals, to be used permanently in a pre-defined and dedicated location, and de-installed by professionals.
Large-scale stationary industrial tools	The large-scale assembly of machines, equipment and/or components, functioning together for a specific application, which are permanently installed and de-installed by professionals at a given place and used and maintained by professionals in an industrial manufacturing facility or research and development facility.
Manufacturer	Any supply of an EEE (on the EU market) for distribution, consumption or use in the course of a commercial activity and markets it under their own name/trademark.
Medical device	Any instrument, apparatus, appliance, material or other article, including necessary software, intended by the manufacturer to be used for medical purposes on human beings, whether alone or in combination with other equipment.
Monitoring and control instruments	Monitoring and control instruments that are not designed exclusively for industrial professional use.
Non-road mobile machinery	Machinery with an onboard power source that is made exclusively for professional use.
Placing on the market	When a product that has completed its manufacturing stage is made available for distribution or sale for the first time in the EU.
Presumption of conformity	EEE that conforms to a harmonised standard and that has been published in the <i>Official Journal of the European Union</i> is presumed to comply with the regulations.
Recall	Any measure aimed at achieving the return of a product.
Statutory Instrument	Principal form in which delegated/secondary legislation is made in the UK.
Technical file	Technical documentation intended to provide information on the design, manufacture and operation of a product.
Withdrawal	Any measure aimed at preventing a product in the supply chain from being made available on the market.

Appendix 1

Exemptions: medical devices and monitoring and control instruments

The applications listed below have been exempted from the new product categories, such as medical devices and monitoring and control instruments, introduced by RoHS 2.

Equipment utilising or detecting ionising radiation

- lead, cadmium and mercury in detectors for ionising radiation
- lead bearings in X-ray tubes
- lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate
- lead in glass frit of X-ray tubes and image intensifiers and lead in glass frit binder for assembly of gas lasers and for vacuum tubes that convert electromagnetic radiation into electrons
- lead in shielding for ionising radiation
- lead in X-ray test objects
- lead stearate X-ray diffraction crystals
- radioactive cadmium isotope source for portable X-ray fluorescence spectrometers.

Sensors, detectors and electrodes

- lead and cadmium in ion-selective electrodes including glass of pH electrodes
- lead anodes in electrochemical oxygen sensors
- lead, cadmium and mercury in infra-red light detectors
- mercury in reference electrodes: low-chloride mercury chloride, mercury sulphate and mercury oxide.

Others

- cadmium in helium-cadmium lasers
- lead and cadmium in atomic absorption spectroscopy lamps
- lead in alloys as a superconductor and thermal conductor in magnetic resonance imaging (MRI)
- lead and cadmium in metallic bonds to superconducting materials in MRI and SQUID detectors
- lead in counterweights
- lead in single crystal piezoelectric materials for ultrasonic transducers
- lead in solders for bonding to ultrasonic transducers
- mercury in very high-accuracy capacitance and loss measurement bridges and in high-frequency radio-frequency switches and relays in monitoring and control instruments not exceeding 20mg of mercury per switch or relay
- lead in solders in portable emergency defibrillators
- lead in solders of high-performance infrared imaging modules to detect in the range 8–14µm
- lead in liquid crystal on silicon displays
- cadmium in X-ray measurement filters.

Appendix 2

Exemptions: other applications

This table lists the exemptions first granted under Annex III of the RoHS Directive 2002/95/EC, by restricted substance. In many cases, the exemptions have expired or the permitted limits have been reduced. These changes are shown in the 'current status' column.

Product/material	Exemption	Current status
Mercury exemptions		
Single-capped (compact) fluorescent lamps, less than 30W	5mg per burner	Expired: new limit of 2.5mg per burner since 1 January 2013
Single-capped (compact) fluorescent lamps, between 30W and 49W	5mg per burner	Expired: new limit of 3.5mg per burner since 1 January 2012
Single-capped (compact) fluorescent lamps, between 50W and 149W	5mg per burner	Unchanged
Single-capped (compact) fluorescent lamps, 150W or more	15mg per burner	Unchanged
Single-capped (compact) fluorescent lamps, circular or square, with tube diameter up to 17mm	No limitation	Expired: new limit of 7mg per burner since 1 January 2012
Single-capped (compact) fluorescent lamps for special purposes	5mg per burner	Unchanged
Double-capped linear tri-band phosphor fluorescent lamps, normal life, tube diameter less than 9mm	5mg per lamp	Expired: new limit of 4mg per lamp since 1 January 2012
Double-capped linear tri-band phosphor fluorescent lamps, normal life, tube diameter between 9mm and 17mm	5mg per lamp	Expired: new limit of 3mg per lamp since 1 January 2012
Double-capped linear tri-band phosphor fluorescent lamps, normal life, tube diameter between 18mm and 28mm	5mg per lamp	Expired: new limit of 3.5mg per lamp since 1 January 2012
Double-capped linear tri-band phosphor fluorescent lamps, normal life, tube diameter more than 28mm	5mg per lamp	Expired: new limit of 3.5mg per lamp since 1 January 2013

Exemptions: other applications *continued*

Product/material	Exemption	Current status
Mercury exemptions		
Double-capped linear tri-band phosphor fluorescent lamps, long life	8mg per lamp	Expired: new limit of 5mg per lamp since 1 January 2012
Linear halophosphate lamps, tube diameter more than 28mm	10mg per lamp	Expired
Non-linear halophosphate lamps, all diameters	15mg	Expires on 13 April 2016
Non-linear tri-band phosphor lamps, tube diameter less than 17mm	No limitation	Expired: new limit of 15 mg per lamp since 1 January 2012
Lamps for other general lighting and special purposes (for example, induction lamps)	No limitation	Expired: new limit of 15mg per lamp since 1 January 2012
Cold-cathode fluorescent lamps and external-electrode fluorescent lamps (CCFL and EEFL) for special purposes, short length (up to 500mm) 3(a)	No limitation	Expired: new limit of 3.5mg per lamp since 1 January 2012
Cold-cathode fluorescent lamps and external-electrode fluorescent lamps (CCFL and EEFL) for special purposes, medium length (between 501mm and 1,500mm)	No limitation	Expired: new limit of 5mg per lamp since 1 January 2012
Cold-cathode fluorescent lamps and external-electrode fluorescent lamps (CCFL and EEFL) for special purposes, long (more than 1,500mm)	No limitation	Expired: new limit of 13mg per lamp since 1 January 2012
Other low-pressure discharge lamps	No limitation	Expired: new limit of 15mg per lamp since 1 January 2012
High-pressure sodium (vapour) lamps with improved colour-rendering index of more than 60, up to 155W	No limitation	Expired: new limit of 30mg per burner since 1 January 2012

Product/material	Exemption	Current status
Mercury exemptions		
High-pressure sodium (vapour) lamps with improved colour rendering index of more than 60, between 156W and 405W	No limitation	Expired: new limit of 40mg per burner since 1 January 2012
High-pressure sodium (vapour) lamps with improved colour rendering index of more than 60, more than 405W	No limitation	Expired: new limit of 40mg per burner since 1 January 2012
Other high-pressure sodium (vapour) lamps, up to 155W	No limitation	Expired: new limit of 25mg per burner since 1 January 2012
Other high-pressure sodium (vapour) lamps, between 156W and 405W	No limitation	Expired: new limit of 30mg per burner since 1 January 2012
Other high-pressure sodium (vapour) lamps, more than 405W	No limitation	Expired: new limit of 40mg per burner since 1 January 2012
High-pressure mercury (vapour) (HPMV) lamps	No limitation	Expires on 13 April 2015
Metal halide (MH) lamps	No limitation	Unchanged
Other discharge lamps for special purposes	No limitation	Unchanged
Mercury used as a cathode sputtering inhibitor in direct-current plasma displays containing up to 30mg per display	No limitation	Expired

Exemptions: other applications *continued*

Product/material	Exemption	Current status
Lead exemptions		
Glass of cathode-ray tubes	No limitation	Unchanged
Glass of fluorescent tubes	0.2% by weight	Unchanged
Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0.35% lead by weight	0.35% by weight	Unchanged
Lead as an alloying element in aluminium	0.4% by weight	Unchanged
Copper alloy containing up to 4% lead by weight	4% by weight	Unchanged
High melting-temperature solders containing 85% or more of lead by weight	No limitation	Unchanged
Solders for servers, storage and storage array systems, network infrastructure equipment for switching, signalling, transmission, and network management for telecommunications	No limitation	Unchanged
Components in a glass or ceramic component other than dielectric ceramic in capacitors, for example piezoelectronic devices, or in a glass or ceramic matrix compound	No limitation	Unchanged
Dielectric ceramic in capacitors for a rated voltage of 125V AC or 250V DC or higher	No limitation	Unchanged
Dielectric ceramic in capacitors for a rated voltage of less than 125V AC or 250V DC	No limitation	Expired on 1 January 2013; however, the exemption continues to apply to spare parts placed on the market before that date
PZT-based dielectric ceramic materials for capacitors that are part of integrated circuits or discrete semiconductors	No limitation	Expires on 21 July 2016

Product/material	Exemption	Current status
Lead exemptions		
Bearing shells and bushes for refrigerant-containing compressors for heating, ventilation, air conditioning and refrigeration (HVACR) applications	No limitation	Unchanged
C-press compliant pin connector systems	No limitation	Expired; however, the exemption continues to apply to spare parts for EEE placed on the market before 24 September 2010
Other compliant pin connector systems	No limitation	Expired on 1 January 2013; however, the exemption continues to apply to spare parts placed on the market before that date
Coating materials for the thermal conduction module C-ring	No limitation	Expired; however, the exemption continues to apply to spare parts for EEE placed on the market before 24 September 2010
White glass used for optical applications	No limitation	Unchanged
Solders consisting of more than two elements for the connection between the pins and the package of microprocessors containing between 80% and 85% of lead by weight	No limitation	Expired on 1 January 2012; however, the exemption continues to apply to spare parts placed on the market before that date
Solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages	No limitation	Unchanged
Linear incandescent lamps with silicate-coated tubes	No limitation	Expires on 1 September 2013

Exemptions: other applications *continued*

Product/material	Exemption	Current status
Lead exemptions		
Lead halide as radiant agent in high-intensity discharge (HID) lamps used for professional reprography applications	No limitation	Unchanged
Lead as activator in the fluorescent powder 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)	1% lead by weight	Expired
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 (BaSi2O5:Pb)	No limitation	Unchanged
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)	No limitation	Expired
Lead oxide in glass used for bonding front and rear substrates of flat fluorescent lamps used for liquid crystal displays (LCDs)	No limitation	Expired
Printing inks for the application of enamels on glass, such as borosilicate and soda lime glass	No limitation	Unchanged
Finishes of fine-pitch components other than connectors with a pitch of 0.65mm and less	No limitation	Expired; however, the exemption continues to apply to spare parts for EEE placed on the market before 24 September 2010

Product/material	Exemption	Current status
Lead exemptions		
Solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors	No limitation	Unchanged
Lead oxide in surface conduction electron-emitter displays (SED) used in structural elements, notably in the seal frit and frit ring	No limitation	Unchanged
Lead oxide in the glass envelope of black light blue lamps	No limitation	Expired
Lead alloys as solder for transducers used in high-powered loudspeakers	No limitation	Expired
Lead bound in crystal glass	No limitation	Unchanged
Soldering materials in mercury-free flat fluorescent lamps	No limitation	Unchanged
Lead oxide in seal frit used for making window assemblies for argon and krypton laser tubes	No limitation	Unchanged
Solders for soldering of thin copper wires of 100µm diameter and less in power transformers	No limitation	Unchanged
Lead in cermet-based trimmer potentiometer elements	No limitation	Unchanged
Lead in the plating layer of high-voltage diodes on the basis of a zinc borate glass body	No limitation	Unchanged
Filter glasses and glasses used for reflectance standards	No limitation	Unchanged

Exemptions: other applications *continued*

Product/material	Exemption	Current status
Cadmium exemptions		
Printing inks for the application of enamels on glasses, such as borosilicate and soda lime glasses	No limitation	Unchanged
One-shot pellet type thermal cut-offs	No limitation	Expired on 1 January 2012; however, the exemption continues to apply to spare parts placed on the market before that date
Electrical contacts	No limitation	Unchanged
Thick film pastes used on aluminium bonded beryllium oxide	No limitation	Unchanged
Colour-converting II-VI LEDs (<10µg Cd per mm ² of light-emitting area) for use in solid state illumination or display systems	No limitation	Expires on 1 July 2014
Photoresistors for analogue optocouplers applied in professional audio equipment	No limitation	Expires on 31 December 2013
Filter glasses and glasses used for reflectance standards	No limitation	Unchanged
Cadmium alloys as electrical/mechanical solder joints to electrical conductors located directly on the voice coil in transducers used in high-powered loudspeakers	No limitation	Unchanged
Hexavalent chromium exemptions		
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	Unchanged

