

RoHS 2 FAQ

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Preface

In this document, Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE) is referred to as RoHS 1 and the recast Directive 2011/65/EU is referred to as RoHS 2.

Directive 2011/65/EU entered into force on 21st July 2011 and requires Member States to transpose the provisions into their respective national laws by 2nd January 2013. The RoHS 2 Directive is part of the European Union's horizontal waste management legislation.

This Frequently Asked Questions (FAQ) document is principally intended to help economic operators interpret the provisions of RoHS 2 in order to ensure compliance with the Directive's requirements. However, the Directive being addressed only to the Member States, the rights and obligations for private parties exclusively flow from the measures enacted by the authorities of the Member States to implement it.

The FAQ is considered a 'living document' and may be revised in the future, according to the experience with the implementation and review of RoHS 2.

These FAQ reflect the views of DG Environment and as such are not legally binding: binding interpretation of EU legislation is the exclusive competence of the Court of Justice of the European Union.

These FAQ should be read in conjunction with the general principles of the New Legislative Framework (NLF) and the Commission's guide to the implementation of directives based on the New Approach and the Global Approach (hereafter referred to as the Blue Guide)¹. If the Commission proposes any changes to the scope of RoHS 2 following an Impact Assessment then this document may undergo significant changes.

¹ <http://ec.europa.eu/enterprise/policies/single-market-goods/documents/blue-guide/>

1. General

Q1.1 What was the intention behind the RoHS-recast?

The RoHS-recast was mainly aimed at

- developing better regulatory conditions. That means a simple, effective and enforceable Directive;
- increasing the level of legal clarity and certainty, including the facilitation of its harmonised enforcement;
- the adaptation of the Directive to the technical and scientific progress concerning the use of hazardous substances in EEE particularly in medical devices and monitoring and control instruments;
- aligning and harmonising RoHS with other EU legislation, such as the New Legislative Framework - 'Marketing of Products Package', REACH², the ErP Directive³ and legislation related to management of waste from EEE with the objective to reduce administrative burden and to increase cost effectiveness;
- harmonising the implementation made in the different Member States; and
- preventing risks to human health and the environment, with a particular focus on workers involved in the management of electronic waste.

Q1.2 What is the difference between Directive 2002/95/EC (RoHS 1) and Directive 2011/65/EU (RoHS 2)?

There are key differences between RoHS 1 and RoHS 2 in the following areas:

1. Scope
 - a gradual extension of the requirements to all electrical and electronic equipment (EEE), cables and spare parts with a view to full compliance by 22nd July 2019;
 - a clarification of important definitions;
2. Restriction of new substances
 - a methodology for the assessment of new hazardous substances in EEE with a view to restriction mainly based on waste-related criteria;
 - a review of the list of restricted substances carried out by the Commission by July 2014, and periodically thereafter;
 - an opportunity for Member States to propose new substance restrictions;
3. Exemptions:
 - clearer and more transparent rules for granting, renewing or deleting exemptions;
 - obligation of manufacturers to apply for exemptions and to carry out the necessary assessment
4. Coherence with other EU-Legislation:
 - New Legislative Framework (CE marking and Declaration of Conformity); and

² Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.

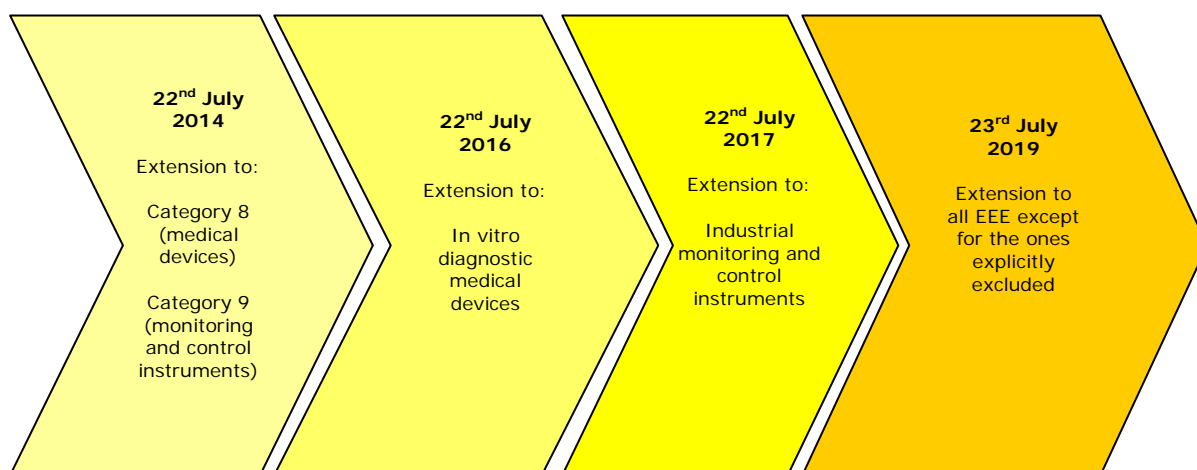
³ Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products.

- Regulation (EC) No 1907/2006 REACH on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Q1.3 When do the new provisions of RoHS 2 apply?

RoHS 2 entered into force on 21st July 2011 and must be transposed into national laws by 2nd January 2013. At that time RoHS 1 will be repealed.

From 22nd July 2014 the substance restrictions will gradually be extended to new product categories. The provisions of RoHS 2 will also apply for these types of EEE⁴ from the dates mentioned below:



Cables, spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity for a specific product category, are in scope from the same date as their respective product category.

The requirements for CE marking and Declaration of Conformity are effective from 2nd January 2013 (see section 9 of this document).

Q1.4 Why are the hazardous substances restricted in RoHS 2 not restricted in all products?

One of the prime objectives of RoHS 2 is to address concerns related to the increasing volume of waste electrical and electronic equipment (WEEE) arising in the EU. Hazardous substances in this type of equipment could be released during waste management processes and could give rise to damage to human health and the environment. The most effective way to address this concern is to restrict the use of the hazardous substances at the point of manufacture. Restricting the use of hazardous substances in EEE at the point of manufacture also reduces the potential exposure of hazardous substances during the use phase where dermal, oral and inhalation exposure can occur. The EU has also legislated on hazardous substances

⁴ Please note that the scope of EEE in RoHS 2 has been clarified and that due to so far existing national implementations on the definition of EEE, category 11 and cables there may be differing interpretations of the old scope in various Member States. This may affect the date of applicability of the provisions of RoHS 2.

in relation to other priority waste streams, such as end-of-life vehicles, batteries and packaging.

Q1.5 How are REACH and RoHS 2 related to each other?

RoHS and REACH are two different acts with different scopes and objectives. RoHS 2 is a sector specific directive laying down rules on the restriction of certain hazardous substances in EEE, while REACH is a general act regulating registration, evaluation, authorization and restriction of chemical substances.

RoHS 2 and REACH apply in parallel. REACH also contains rules on restriction of substances in various applications, but in principle there should be no overlaps, as restrictions of the specific use of substances in EEE should not be addressed by REACH. When overlaps nonetheless occur, the strongest restriction (i.e. the lowest maximum concentration) should be applied. Furthermore, exemptions from the substance restrictions in RoHS 2 may not be granted if they result in a weakening of the environmental and human health protection afforded by REACH.

Recital 28 in RoHS 2 requires that during the review of the Directive, a thorough analysis of its coherence with REACH shall be carried out by the Commission. To secure coherence between RoHS 2 and REACH:

- both the methodology for prospective substance restrictions and the criteria for granting exemptions should be coherent with REACH.
- the available information according to the REACH procedures shall be used for future substance related RoHS amendments.

The first review of RoHS 2 is due by July 2014 and will also address the development of a methodology for any future amendments to the list of restricted substances.

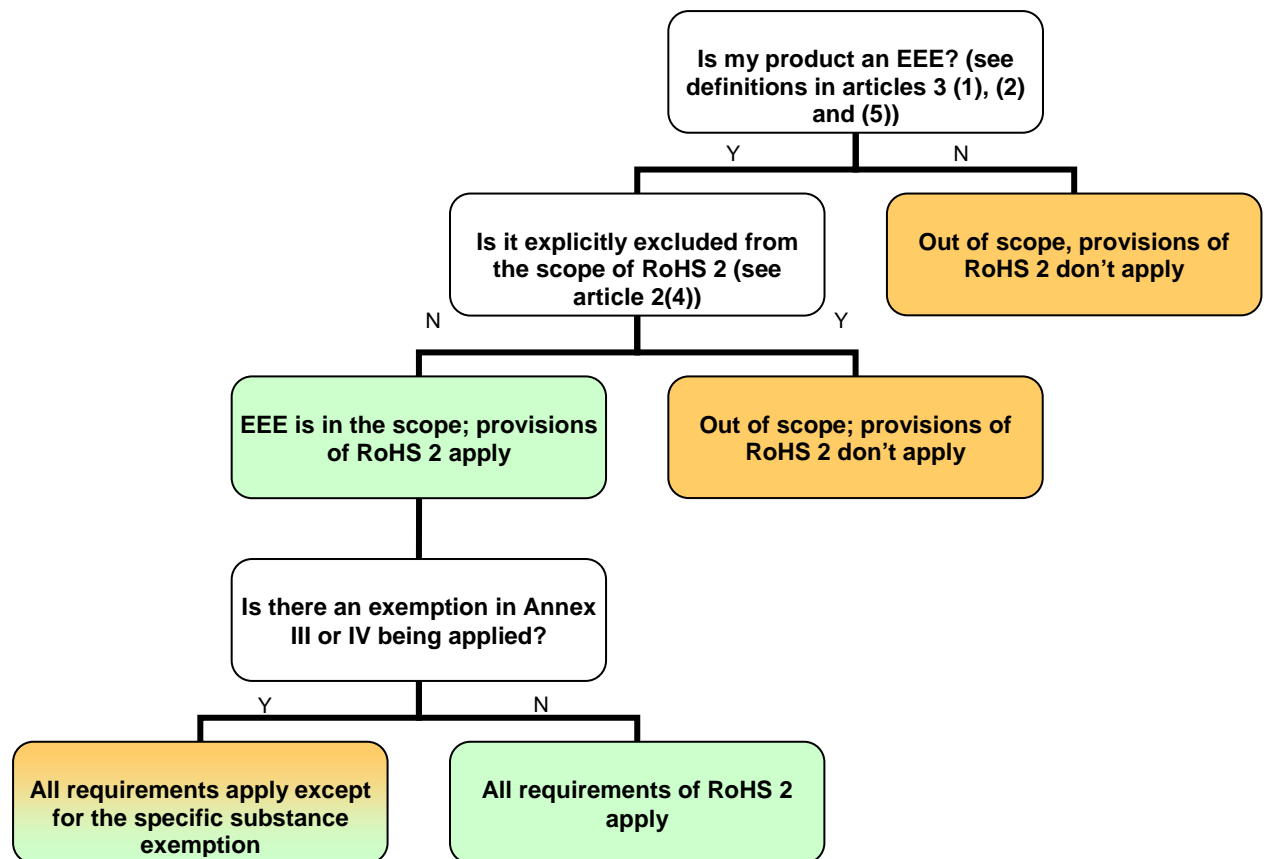
Q1.6 Are batteries within the scope of RoHS?

The batteries and accumulators directive (2006/66/EC⁵) and RoHS 2 have similar substance restrictions. Recital 14 of RoHS 2 specifically states that RoHS should apply without prejudice to the Batteries Directive. Recital 29 of the batteries and accumulators directive states RoHS 1 does not apply to batteries and accumulators used in electrical and electronic equipment.

Q1.7 How can I find out if RoHS 2 applies to my product?

To find out if the requirements of RoHS 2 apply to your product follow the decision tree below:

⁵ Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC.



Q1.8 Where can I ask questions about the provisions of RoHS 2?

If you have any questions, please contact the national authorities. A list of national authorities can be found here:

http://ec.europa.eu/environment/waste/weee/pdf/contacts_ms_rohs.pdf

2. Scope – Article 2.2

Q2.1 What does "Without prejudice to Article 4(3) and 4(4), Member States shall provide that EEE that was outside the scope of Directive 2002/95/EC, but which would not comply with this Directive, may nevertheless continue to be made available on the market until 22 July 2019" mean?

Article 2(2)⁶ of RoHS 2 states that non-compliant EEE that were outside the scope of RoHS 1 but inside the scope of RoHS 2 must be granted full market access until 22 July 2019, unless the granted transition period is limited via Articles 4(3) and 4(4).

⁶ Commission Declaration on the scope (Article 2(2))
<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2010-0431+0+DOC+XML+V0//EN#BKMD-9>

Q2.2 What does “making available on the market” mean in this context? (Articles 2(2), 3(11), 3(12))

Making available on the market includes the placing on the market, i.e. the first making available (on the market) and all secondary market operations, for example resale. This means that the products benefiting from Article 2(2) will have full market access until 22 July 2019. However, after that date none of these products shall be allowed to remain on the market even if they have been placed there before that date. This means that the distribution chain within the EU must be clear of these non-compliant products by 22 July 2019.⁷

Q2.3 Which products benefit from this provision? (Articles 2(2), 2(1), 3(1), 3(2), 4(3), 4(4))

All category 11 products may benefit from the transitional period of Article 2(2), but also products in other categories that only now fall within the scope of RoHS 2 due to a new scope related provision, such as the clarified definition of EEE, which comprises any piece of equipment that needs electric currents or electromagnetic fields for at least one intended function.⁸

Q2.4 What does "non-compliant" mean? (Articles 2(2), 4(1), 4(2), 13, 15)

Non-compliant means products that do not comply with the maximum concentration values, or that do not comply with the procedural requirements under RoHS 2 (i.e. Declaration of Conformity and CE marking).

3. Scope – Large-scale exclusions

Q3.1 What are "large-scale stationary industrial tools" and "large-scale fixed installations"? (Articles 2(4)(d) and 2(4)(e))

Unlike RoHS 1, RoHS 2 has an open scope. However, several product groups are excluded from the RoHS 2 scope. Two of the exclusions listed in Article 2(4) refer to combinations of EEE in a professional context, i.e. "large-scale stationary industrial tools" (Article 2(4) (d)) and "large-scale fixed installations" (Article 2(4) (e)).

Both terms are explained in the definitions (Articles 3(3) and 3(4)), however it is not explained what "large-scale" means. Both categories are combinations of various types of items, such as machinery, components etc. for permanent use at a specific place, installed and de-installed by professionals. Therefore the two categories may overlap. However, it is important to consider that the meaning of "large-scale" in absolute terms may be a different one for tools and installations, as there are differences between tools and installations.

⁷ The analysis of the impact of this provision ("hard stop" July 2019) is part of the ongoing impact assessment; see also preface.

⁸ Please note that the RoHS 1 scope was based on WEEE 1. Some Member States took a broader scope interpretation. As a result, how Article 2(2) is applied will also depend on Member States' implementation of RoHS 1.

Tools are essentially machines, stand-alone or assemblies, often with moving parts, and used for example for the treatment and manufacturing of materials and work pieces. The Machinery Directive⁹ can be used as guidance. Typical machine tools can also be part of fixed installations.

In order to benefit from either exclusion the tool or installation must meet all the respective requirements. As stated below, it has to be:

(Tool)

- an assembly of machines, equipment and/or components, functioning together for a specific application;
- permanently installed and de-installed by professionals at a given place;
- used and maintained by professionals in an industrial manufacturing facility or R&D facility;
- and it has to be large-scale;

(Installation)

- a combination of several types of apparatus and, where applicable, other devices;
- assembled, installed and de-installed by professionals;
- with the intention to be used permanently in a pre-defined and dedicated location;
- and it has to be large-scale.

"Large-scale" is part of both sets of requirements. Evidently, this draws a line between large tools and installations benefiting from an exclusion, and otherwise similar, smaller equipment. "Large-scale" primarily refers to dimensional criteria, although this criterion is not specified in the RoHS 2.

It is the responsibility of the manufacturer/assembler/user's responsibility to assess whether he thinks his tool or installation benefits from either exclusion. Where a combination of equipment, components and sub-assemblies is being brought together or combined and placed on the market as a single piece of equipment then consideration could be given to application of other directives such as the Electromagnetic Compatibility (EMC), Low Voltage and Machinery Directives.

Due to the nature of both exclusions, in case of doubt, decisions are to be taken on a case-by-case basis. The purpose of the following non-exhaustive lists of examples and criteria is to support those decisions.

Examples for large-scale fixed installations (benefiting from an exclusion):

- Production and processing lines, including robots and machine tools (industrial, food, print media etc.);
- Passenger lifts;
- Conveyor transport systems;
- Automated storage systems;

⁹ <http://ec.europa.eu/enterprise/sectors/mechanical/documents/legislation/machinery/>

- Larger fixed installed cooling, air conditioning and refrigerating systems of more than 12 kW nominal cooling capacity, or heating systems with a nominal capacity higher than 70 kW, or ventilating systems with a power input above 125 W, insofar as they are not intended for domestic use.

PICTURES (industry input)

Examples of large-scale stationary industrial tools (benefiting from an exclusion):

- Machines for the industrial production and processing of materials and goods, such as CNC lathes or bridge-type milling and drilling machines, and other machinery of similar size and weight;
- Assembly cranes.

PICTURES (industry input)

Buildings and sites, chemical plants etc. are not installations; however they may be comprised of various subsystems that can be addressed as installations or tools pursuant to RoHS 2. The key characteristic of a subsystem is that its elements are interdependent and connected. Some subsystems may be outside the scope of RoHS 2 from the start, as they do not comprise EEE, or may be excluded installations or tools. EEE that is specifically designed for such subsystems outside the scope of RoHS 2, also benefits from the exclusion via Article 2(4)(c).

As a general rule, bench top tools and IT equipment do not fall within the category of large-scale stationary industrial tools.

Tools and installations that do not fall within the examples above should be assessed individually with respect to the wording of the exclusions. **The burden of proof is with the manufacturer, assembler, and user.**

Machinery that has partial mobility, for example semi-mobile machinery running on rails, can be of 'permanent use'. On the other hand, EEE that is intended to be used on different sites during its life is not considered as permanent. It is an indicator of permanent use if the equipment is not readily re-locatable (or 'mobile intended') and if it is intended for use at one single location.

As for the industrial context for professional installation and de-installation, scenarios such as the need for special assembling equipment, required permits, if the commissioning is a professional engineering exercise, specialised training, considerable installation time etc. can be indicator.

As regards "large-scale", this is especially relevant to tools such as stand-alone industrial machines placed individually on the market. "Large-scale" can be used to identify and differentiate between tools because of their size, weight, capacity, throughput or other performance related criteria. It also relates to tool or installation complexity, and to the effort needed for installing, operating, maintaining and de-installing a tool or an installation. One possible way of introducing a direct size criterion relates to transportation. The following guidance metrics and qualitative

criteria can be applied for installations. If the installation exceeds the minimum requirements for **one** of the following criteria, it can be considered large-scale:

- If, when installing or de-installing the installation, it is too large to be moved in an ISO 20 foot container because the total sum of its parts as transported is larger than 5,71m x 2,35m x 2,39m, then it can be considered large-scale.
- The maximum weight of many road trucks is 44 tonnes. Thus if, when installing or de-installing the installation, it is too heavy to be moved by a 44 tonne road truck, because the total sum of its parts as transported weighs more than the truck's load capacity, it can be considered large-scale.
- If heavy-duty cranes are needed for installation or de-installation, the installation can be considered large-scale.
- An installation that does not fit within a normal industrial environment, without the environment needing structural modification, can be considered large-scale. Examples for modifications are modified access areas, strengthened foundations etc.
- If an installation has a rated output greater than 375 kW, it can be considered large-scale.

This is only an indicative list.

As explained above, "large-scale" does not necessarily have the same meaning for tools and installations. Tools that are large in comparison to smaller industrial tools can be significantly smaller than large installations. Therefore, tools matching the above listed criteria for installations are in any case large-scale. The following criteria can be applied to tools, but specific guidance metrics are still in development.¹⁰

- Dimensions (for guidance see above listed examples of tools);
 - o Tool size;
 - o Size, movement or force of moving parts;
- Weight (for guidance see above listed examples of tools).

Where the size or weight of a tool or an installation is close to the guidance metrics for large-scale, or where it is difficult to determine its exact size or weight with regard to its classification as large-scale, complexity may be taken into consideration as a qualitative indicator. This may include requiring special power connections and utility connections other than clean dry air or water supply and drain, such as high pressure compressed gas supply, vacuum lines or chemical supply lines and drains.

Q3.2 Does the LSSIT/LSFI scope exclusion also cover equipment such as industrial monitoring and control instruments?

Like the recast WEEE Directive (WEEE 2)¹¹, RoHS 2 covers both EEE used by consumers and EEE intended for professional use. WEEE 2 Recital 9 states that the

¹⁰ In order to ensure legal certainty, specific guidance metrics for large-scale tools based on available technical data should be developed in the course of the implementation and enforcement of RoHS 2, and incorporated in a revised version of this guidance document. The benchmarks for large tools should be between and significantly different from those for large household appliances as currently discussed under WEEE 2, and those for large installations as listed in this document.

¹¹ Position of the European Parliament adopted at second reading on 19 January 2012 with a view to the adoption of Directive 2012/.../EU of the European Parliament and of the Council on waste electrical

objectives of this Directive can be achieved without including large-scale fixed installations within its scope. However, any equipment which is not specifically designed and installed as part of these installations, which can fulfil its function even if it is not part of these installations, should be included in the scope of this Directive. The same principle applies to RoHS 2, where smoke detectors, computers and cables are examples of equipment that are in scope.

Q3.3 Who is responsible for items that are to be used in LSSIT/LSFIs?

Pursuant to Article 2 (4)(c), read in conjunction with Article 2 (4)(d) and (e), RoHS 2 does not apply to equipment which is specifically designed, and is to be installed, as part of LSSIT or LSFI. Whilst the obligations which the Directive imposes on the manufacturer of EEE and the different actors in the distribution chain will therefore not apply as such with regard to said equipment, a given manufacturer may nevertheless have to ensure and establish that the conditions laid down in Article 2 (4)(c) are fulfilled. The other actors may then have to provide documentation and information to this extent. Despite the absence of installers' obligations in the text of the RoHS Directive, one cannot exclude that the installer who does not manufacture the equipment at issue would have to bear such documentation and information responsibilities.

4. Scope – Other exclusions

Q4.1 What is meant by “the same specifically designed equipment” (Article 2(4)c and Article 2(4j))

“Specifically designed” equipment is mentioned in two of the Directive’s exclusions (Article 2(4)(c) and Article 2(4)(j)). All exclusions in Article 2(4) are exclusive to their nature. This means that equipment that can be used according to the exclusion, but also for purposes within the scope of RoHS 2, will need to comply. The wording “specifically designed”, as stated in Article 2(4)(c) and Article 2(4)(j), reflects this principle.

The exclusion in Article 2(4)(c) applies to equipment that is specifically designed to be fitted into another piece of equipment.

Specifically designed EEE normally means that it is tailor made; it is designed to meet the need of a specific application. For example, for EEE to be specifically designed to a LSFI it needs to be designed, dimensioned and customised according to the need of the application.

Examples of specifically designed include sensor equipment designed to fit inside drill heads and galley equipment designed for an individual aircraft or range of aircraft. Examples that are not specifically designed include standard electronic racking systems, and other non-standard equipment intended to be fitted to an automobile such as hands-free phone systems and satellite navigation devices.

and electronic equipment (WEEE) (Recast): <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0009+0+DOC+XML+V0//EN#BKMD-9>

The exclusion in Article 2(4)(j) applies to equipment that is designed for the sole purpose of research and development. Equipment that could be used for R&D purposes, but also for example monitoring and control, do not benefit from the exclusion but should comply with the requirements. See also Q4.2 about the R&D exclusion.

Q4.2 Is R&D equipment excluded from RoHS 2?

Equipment specifically designed solely for the purpose of research and development, which is made available solely on a business-to-business basis, are excluded from the scope of RoHS 2. This is because if this type of equipment were to fall within scope of RoHS 2, it could place a burden on research, development and innovation in the EU.

This exclusion will only apply to specialised EEE that are custom built solely for very specific R&D applications. Standard equipment such as monitoring devices or instruments for chemical analysis and other laboratory equipment that can be used both for R&D applications and in commercial or other applications, will not benefit from this exclusion. Neither does it apply to equipment designed and put on the market to test, validate or monitor R&D equipment and/or prototypes as that equipment would belong to category 9.

In order to benefit from the R&D exclusion, the equipment concerned should be custom made for a specific client or a small number of clients involved in scientific research or prototype product development.

Examples of EEE that may benefit from this exclusion include:

- non-finished products such as prototype or sample/test EEE
- in-house custom built “development vehicles” used solely for development, test, validation and evaluation of such non-finished products, including the evaluation of regulatory compliance, product performance and determination of customer acceptability

This type of EEE belongs to the conceptual, developmental, design or pre-production stage and is as such designed for R&D use.

Q4.3 Are EEE built into buildings outside of scope?

No, Article 2(4)(c) refers to “another type of equipment” which is outside the scope of the directive. Buildings are not considered equipment for the purposes of RoHS 2. Therefore equipment that is installed in a building cannot be excluded on the basis of Article 2.4(c). Installations in a building may be excluded if they meet the criteria of LSSIT or LSFI; please see section 3 for guidance.

Q4.4 What is meant by “multiple” or “dual” use?

EEE with “multiple use” have uses that are inside and outside the scope (EEE that meets the definition of Article 2(4) or EEE that does not meet the definition of Article 3(1) and 3(2) or 3(5)).

The term “dual use” is widely used by industry and enforcement authorities in the same sense as “multiple use” above. In the context of the WEEE Directive

(2002/96/EC), “dual use” however refers to the distinction between consumer and professional use. This distinction is not relevant in RoHS 2; the same requirements are applied to EEE regardless of their sector of use.

Q4.5 If EEE has multiple uses of which one is in the scope of RoHS 2, does the EEE have to comply”?

EEE that is intended to have at least one use within the scope of RoHS 2 has to comply with the provisions of the directive. For instance, a fridge that could be installed in either a commercial vehicle and therefore would be excluded via Article 2(4)(f) in conjunction with Article 2(4)(c). A fridge in a hotel room will have to comply with RoHS 2 as no exclusion applies. Non-road mobile machinery that is made available to both professionals and consumers, for example via their point of sale, will also have to comply. Likewise, EEE that can be used for the protection of the essential interests of the security of Member States, but has also other uses, will be in scope and have to comply.

The term ‘intended use’ is explained in the Blue Guide.

Q4.6 Can multiple use EEE that is non-compliant be sold for the use in excluded products?

When a non-compliant EEE is placed or made available on the market for an excluded use, the economic operator placing it or making it available on the market is responsible for having full knowledge of the possible uses of the equipment. Therefore the economic operator is responsible for assuring that the EEE is only sold for the uses outside of the scope of RoHS 2.

5. Scope – Cables

Q5.1 Are cables within the scope of RoHS 2?

Cables are within the scope of RoHS 2 if they meet the definitions of EEE in Article 3(1) or of cables in Article 3(5). Most types of cables will meet these definitions as cables are both dependent on electrical currents and electromagnetic fields to work properly and are primarily used for the transfer of electrical currents and electromagnetic fields.

Cables can form part of EEE that has been placed on the market or they can either be placed on the market as a standalone piece of EEE or as a spare part. In addition, cables can either be ‘simple’ or ‘multi-use’ or they can be ‘dedicated’ or ‘specialised’.

Cables can also be either internally integrated (intrinsic) to EEE or they can be externally connected (extrinsic) to EEE. Therefore clarity is needed to distinguish between ‘internal’ and ‘external’ cables.

Q5.2 Are internal wires in EEE ‘cables’?

Internal cables are not ‘cables’ per se but are internal wiring with specific functions contained within or integral to the EEE. Internal wiring connects individual components within EEE and they do not therefore meet the definition of ‘cables’ in

Article 3(5). However, internal wiring is intrinsic to the EEE itself. Internal wiring in any EEE that is within the scope of RoHS 2 must meet the material restrictions like all other parts of the EEE. In the case of internal wiring in EEE where that EEE is outside of the scope, there are no material restrictions for the internal wiring. If the EEE is subject to a scope transition period, the same applies to the internal wiring.

A cable that connects EEE to the electrical outlet or connects two or more EEE to each other is not an internal cable even though parts of the cable are inside the EEE.

Q5.3 Are external cables within the scope of RoHS 2?

External cables that meet the definition of cables in Article 3(5) are within the scope of RoHS 2. Articles 4.1 and 4.4 also state that cables are within the scope of RoHS 2. However, the date on which cables are required to be RoHS 2 compliant is dependent on which category in Annex I the cable is placed in. In order to place a cable in a specific category in Annex I, the type and intended use of the cables as well as the provisions in Article 4.4 have to be taken into consideration.

Q5.4 How does RoHS 2 address the more specialised external cables?

Specialised cables like SCART-cables, HDMI-cables, fibre-cables and network-cables, which are used for example in voice, data and video transfer, are in categories 3 or 4. These cables were thus already within the scope of RoHS 1 and are therefore within the scope of RoHS 2 and must be compliant.

Q5.5 What are the requirements in RoHS 2 for external cables placed on the market together with EEE?

Some cables are marketed together with or connected to EEE. If a cable is connected to EEE, this cable follows the same requirements as the EEE, just like an internal cable. Therefore, if the EEE is within the scope of RoHS 2, then so is the cable connected to it. If the EEE is within the scope of RoHS 2, but not RoHS 1 and a transitional period applies, the same requirements apply for the cable. If the EEE is outside the scope of RoHS 1 & 2, this also applies to the cable and is therefore out of scope. In summary, if cables are marketed with or connected to EEE that is placed on the market and required to be RoHS 2 compliant then the cable itself should also be RoHS 2 compliant.

If a cable is placed on the market together with an EEE then the cable follows the same requirements as that EEE in the same manner as if it was connected to the EEE.

Q5.6 What are the requirements in RoHS 2 for external cables placed on the market individually as separate products?

For external cables placed on the market individually, a distinction is also made between cables with connectors in both ends and those cables with no connectors in either one or two ends. All cables that are placed on the market individually as separate or standalone EEE will need to be accompanied by a Declaration of Conformity and be CE marked.

Simple or multi-use cables for the transfer of electrical current with connectors at both ends should be placed in category 2 of Annex I. Examples of simple or 'multi-use' cables include 'ready for use' cables like power extension cords, cable rollers, and

multiple socket-outlets with cables. In addition, relatively simple cables such as USB-cables are placed in category 2.¹²

Cables that are placed on the market individually and can only be used for a specific EEE then that cable follows the same requirements as that specific EEE as if they were placed on the market together. However the cable falling within the scope and placed on the market separately will need its own Declaration of Conformity and be CE marked.

External simple or multi-use cables with one or no connectors are placed in category 11. Components or parts of EEE are normally not in the scope of the RoHS 2 however it is generally the case that a cable with one or no connector as such is or is going to be connected to EEE as cables with one or no connector can easily be used to connect to a lamp and thus fulfil the definition in Article 3(5) that relates to Article 4.1. Cables with one or no connector are therefore in the scope of the RoHS 2 and should be placed in category 11.

Cables that are placed on the market individually with a rated voltage higher than 250 volts are not within the scope of RoHS 2.

6. Scope – Consumables

Q6.1 Are consumables in the scope?

Consumables that have no equipment constituent, such as soap powder or vacuum cleaner bags, are not equipment and are therefore not in the scope of RoHS 2. Only consumables with an equipment constituent meeting the definition of EEE in Article 3(1) and 3(2) such as printer cartridges are EEE and in the scope of RoHS 2.

7. General Open Scope

Q7.1 Which types of equipment benefit from the exclusions from the scope?

Non-exhaustive examples of excluded equipment as per the corresponding exclusion in Article 2(4) include the following:

Reference	Summary Exclusion	Example equipment
Article 2(4)(a)	Military/security equipment	Missiles Battlefield computers
Article 2(4)(b)	Designed to be sent into space	Satellites Space probes

¹² Please note that some Member States have not included these cables in category 2 in their transposition of RoHS 1. In these Member States these cables will be subject to the transition period.

Article 2(4)(c)	Part of non-scope equipment	Computers specifically built to be installed in aircraft
Article 2(4)(d)	Large-scale stationary industrial tools (LSSIT)	Production and processing lines Assembly cranes <i>See also Q3.1</i>
Article 2(4)(e)	Large-scale fixed installations (LSFI)	Lifts Conveyor transport systems <i>See also Q3.1</i>
Article 2(4)(f)	Means of transport	Cars, Commercial Vehicles and Aircraft
Article 2(4)(g)	Non-road mobile machinery (NRMM)	Hydraulic excavators Fork-lifts Road maintenance equipment
Article 2(4)(h)	Active implantable medical devices	Pacemakers
Article 2(4)(i)	Photovoltaic panels	Solar arrays
Article 2(4)(j)	R&D equipment	Watt balances <i>See also Q4.2</i>

Q7.2 Where does space begin? Are weather balloons designed to operate at high altitude be excluded via Article 2(4)b?

Article 2(4)b excludes EEE designed to be sent into space. The commonly defined boundary between the Earth's atmosphere and space is the so-called 'Karman line', which is situated in the thermosphere at an altitude of 100 km above sea level. EEE designed to operate at altitudes higher than 100 km above sea level benefits from the exclusion in Article 2(4)b. Weather balloons generally operate in the stratosphere which is at a considerably lower altitude, and are consequently not excluded from scope.

Q7.3 How do I decide which category of EEE a product falls in?

For some categories of EEE such as medical devices, there is sector specific legislation (for example the Medical Devices Directive, 93/42/EEC¹³) which sets out what types of products are included within its respective scope. In these cases, such sector specific legislation has priority.

The assignment of a product to a category relates primarily to the duration of the exemptions and corresponding transitional arrangements. The duration of the exemptions also depends on the equipment category. Detailed information on the duration of exemptions is contained in Q11.4.

¹³ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Regarding transitional arrangements, the qualification as EEE of a specific product is not as important as the initial assessment of whether the product is “new to RoHS 2” or not. Products that are “new to RoHS 2” are not only in the “new” categories 8, 9 and 11, but can also belong to any other category. This decision has to be made on a case-by-case basis.

From 22 July 2019, all provisions in RoHS 2 will apply for all EEE, and therefore the categories will only be relevant for exemptions.

Whilst this is a decision for the manufacturer or importer, guidance can be sought from the competent authority in the Member State where the manufacturer or importer intends to market the product. By request from the competent authority, for example in an enforcement situation, the manufacturer/importer may need to justify its decision.

Q7.4 Does RoHS 2 apply to EEE for professional and industrial use?

Yes. RoHS 2, just as RoHS 1, does not distinguish between EEE for consumer use and EEE for professional and industrial use. All exclusions from the scope are listed in Article 2(4).

Q7.5 Are telecommunication networks in scope?

Yes. RoHS 2 Annex III exemption 7(b), which exempts lead in solder for IT and telecommunication networks sets out that those networks are in scope. The term “IT and telecommunication networks” also includes cable TV and other similar networks.

Q7.6 Are electric boards in scope?

Yes. An electric board, for example a panel board, a software development board or similar, consists of a bare card (or board) upon which various modules are placed. Both the board in itself and the modules placed upon it are usually standard equipment that are within the scope of RoHS 2. Therefore, such items should meet the requirements in RoHS 2.

Bare cards with EEE functions, for example graphics cards for computers are also within the scope of RoHS 2 since they are supplied as finished products and intended to perform an electrical or electronic function. An empty card, i.e. a card with no components or modules mounted, is however not finished EEE.

Q7.7 Are fuse boxes in scope?

Yes. Fuse boxes meet the definition of EEE as set out in Article 3(1), and do not benefit from any exclusion.

Q7.8 Are active RFID tags in scope?

Yes. Active RFID tags are in scope and should comply with RoHS 2 as they meet the definition of EEE as set out in Article 3(1), and do not benefit from any exclusion. They are generally considered category 3.

RFID tags are often used attached to other articles, for example for stock identification or theft control. The RFID tag is in these cases not deemed a part of the article, as it is not intended to function together with the article but rather to be removed prior to use (for example packaging). The requirements of RoHS 2 should therefore apply to

the RFID equipment only and not to the article to which it is attached, unless the attached article is itself EEE and falls under scope.

Q7.9 Does packaging have to comply to RoHS 2?

No. Packaging pursuant to the Packaging and Packaging Waste Directive¹⁴ (94/62/EC) is outside the scope of RoHS 2.

Q7.10 How should “professional use” be interpreted? Does it apply only at the first placing on the market, or also at later stages?

“Professional use”, as referred to in the exclusion of non-road mobile machinery and the definition of industrial monitoring and control, refers to the use phase of the EEE. In order for EEE to be marketed for “professional use”, its intended end user has to be a professional.

It should also be noted that RoHS 2 does not differentiate between EEE for professional or non-professional use other than in a few exclusions. These exclusions explicitly state that the equipment concerned is made available only for professional use, in order for the exclusion to apply.

8. Definition of EEE and requirements for components

Q8.1 Is my product EEE as per Articles 3(1) and (3)2?

There are two elements clarifying the meaning of EEE in RoHS 2:

- a general definition of EEE in article 3.1;
- a definition of “dependent” in article 3.2.

All equipment that has at least one intended function which is dependent on electric current or electromagnetic fields, or that generates or transfers or measures such currents and fields is EEE. Even if the electric function is only a minor element of the equipment, the definition still applies.

Indicative examples of such EEE are:

- a gas cooker with an electrical clock;
- a singing teddy bear; sport shoes with lights;
- petrol powered equipment with an electric spark for ignition, like lawnmowers.

In all these cases the electric function is an intended and integral part of the product’s functionality, and the full functionality of the equipment is at least impaired, i.e. it does not work properly if that electrical function fails. It is irrelevant where the electricity comes from, or if it is the main energy source.

¹⁴ European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste.

In order for a product to be EEE, its electricity dependent functions must in principle be integrated.

For the example of a wardrobe with lights, even if sold as a single unit, a distinction between the piece of furniture and the electric/electronic device the piece is or can be equipped with has to be drawn. If the lighting is EEE in itself and both the lighting and the wardrobe can be separated and used as fully functional separate products, only the electric/electronic equipment (the lighting) is in the RoHS 2 scope. The furniture itself would then be outside the scope.

This scenario is different from the example of power tools, lamps and many other types of EEE, most of which are already in the scope of RoHS 1 and are comprised of various detachable electric/electronic and non-electric/electronic parts, which are however only fully functional in combination. These parts are simply integral parts of EEE and have to meet the respective requirements. This is for example reflected in various existing exemptions for non-electric EEE parts.

The substance restrictions of article 4 apply to the whole equipment. All equipment placed on the market and meeting the definition of EEE is in the scope of RoHS 2 under one of the 11 categories in the new Annex I.

Q8.2 What does dependent on electric currents or electromagnetic fields mean?

Dependent on electrical currents or electrical fields means that such currents and fields pass through the electrical or electronic parts of the EEE to fulfil at least one function. Equipment without any electrical or electronic parts such as compact discs (CDs) and optical cables are outside the scope of RoHS 2.

Q8.3 Do components have to comply with RoHS 2?

RoHS 2 provides that EEE has to meet the requirements of the Directive. Since **equipment consists of different components**, the EEE itself can only meet the substance requirements if all its components and parts meet those requirements, including non-electronic or non-electric components like fasteners or the plastic case of a desktop computer. Therefore components being used in finished EEE which is in the scope of RoHS 2 have to comply with RoHS 2. Components sold as a stand-alone components or if produced to be used in a product benefiting from an exclusion do not have to be CE marked and do not have to comply with the substance requirements.

9. CE marking, conformity assessment procedures including required technical documentation and Declarations of Conformity

The following section covers **specific points relating to RoHS 2** and should be read in conjunction with the Blue Guide¹⁵. The remarks on CE marking requirements refer exclusively to RoHS. CE marking may (also) be required on the basis of other applicable legislation, e.g. Low Voltage directive, EMC, R&TTE, Machinery etc.

¹⁵ http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf

Q9.1 What is the New Legislative Framework?

To remove obstacles to the free circulation of products and to create an efficient and coherent European legal framework with regard to the marketing of products the Commission in 1985 introduced the “New Approach” which was further developed in 1990 by the “Global Approach”. The New Legislative Framework¹⁶ (NLF) constitutes the modernisation of the New and the Global Approach. Regulation 765/2008 sets out the requirements for accreditation and market surveillance relating to the marketing of products¹⁷. Decision 768/2008 sets a common framework for the marketing of products. This includes model provisions to support market surveillance and the application of CE, the marking, definitions of terms commonly used in product legislation (but sometimes used differently at present) and procedures that allow future sectoral legislation to become more consistent and easier to implement. The decision is only binding upon the EU institutions. To be operational, the model provisions of the Decision need to be incorporated into existing Directives when they are next revised. This process is known as “alignment”.

Overall, the objective of the NLF is to help the internal market for goods work better and to strengthen and modernise conditions for placing a wide range of industrial products on the EU-market. The package of measures within the NLF

- improves the market surveillance rules, to better protect both consumers and professionals, including imports from third countries;
- boosts the quality of the conformity assessment of products through clearer and stronger rules on the requirements for the notification of assessment bodies;
- clarifies the meaning of CE marking; and
- establishes a common legal framework for industrial products in the form of a toolbox of measures for use in future legislation.

Q9.2 What is a Declaration of Conformity (DoC)?

When a product is placed on the market the manufacturer or the authorised representative established within the EU are obliged to draw up an EU DoC as part of the conformity assessment procedure. This declaration must ensure that the requirements of the applicable Directive have been satisfied, i.e. with regard to RoHS 2 the electrical or electronic equipment is in compliance with the substance restrictions of RoHS 2. Pursuant to Article 5 of Commission Decision 768/2008/EC (common framework for the marketing of products) legislation requiring a DoC shall provide that a single declaration shall be drawn up in respect of all relevant Community Acts that apply. In light of this, single declarations should be encouraged.

Q9.3 What do I need to include in my Technical Documentation?

Article 7(b) of RoHS 2 requires the manufacturer to draw up the required technical documentation and carry out the internal production control procedure in line with module A of Annex II to Decision No 768/2008/EC (common framework for the marketing of products) or have it carried out on the manufacturer’s behalf. Hence, the requirements for the technical documentation can be found in that same Annex II of

¹⁶ <http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/>

¹⁷ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF>

the Decision under module A. CENELEC have produced a draft standard on technical documentation¹⁸ expanding on the requirements in 768/2008/EC.

Q9.4 How do I handle the transition to CE marking?

All such EEE must be CE marked and include a reference to RoHS 2 (2011/65/EU) on the DoC from the date when the substance restrictions apply. Where EEE falling within the scope of RoHS 2 and meeting the substance restrictions, procedural requirements and other requirements is placed on the market on or after the Directive's entry into force date (21 July 2011), it may be CE marked and include RoHS 2 on its DoC even if the substance restrictions do not yet apply.

Q9.5 Do spare parts need to be CE marked and have a DoC?

The definitions in Article 3 distinguish between EEE (article 3(1)) and spare parts (article 3(27)). Article 4 requires EEE and spare parts to comply with the substance restrictions but the requirements for affixing CE marks under Article 15 only apply to finished EEE. Therefore spare parts that are not EEE (article 3(1)) do not have to be CE marked or have a DoC. Spare parts that are also EEE such as printer cartridges do require to be CE marked and have a DoC.

Q9.6 Do sub-assemblies need to be CE marked?

Sub-assemblies made available that are only intended to be assembled into EEE by the manufacturer or used as spare parts are not EEE and therefore do not need to be separately CE marked or need a DoC.

Some sub-assemblies are separately made available as functional units such as computer network interface cards and graphics cards. These are considered equipment and must meet all relevant requirements.

Q9.7 Do I need to CE mark and have a DoC for RoHS 2 for equipment in categories 8 and 9 and other equipment newly entering the scope before the substance restrictions apply?

Article 2(2) states that non-compliant products that were outside the scope of RoHS 1 but inside the scope of RoHS 2 have full market access until 22 July 2019, unless there are specific application dates in Articles 4(3) and 4(4). For the purposes of Article 2(2), non-compliant not only means that these products do not need to comply with the substance restrictions but also with the procedural requirements under RoHS 2, including DoC and CE marking. Therefore, although there is no transitional phase for the DoC and CE marking, categories 8 and 9 equipment does not need to be CE marked or include 'RoHS 2' on the DoC until the substance restrictions apply. Other EEE outside the scope of RoHS 1 and inside the scope of RoHS 2 will not require CE marking or a DoC for RoHS 2 unless placed on the market from 23 July 2019.

Q9.8 How do I know if a product is already compliant with the substance restrictions, if the transition period is still ongoing?

The information on whether EEE that

- is still subject to the transitional period under RoHS 2 **and**

¹⁸ prEN 50581: Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.

- is bearing a CE mark

is already compliant with the substance requirements will be found in the DoC.

Q9.9 There seems to be duplication between item 1 and item 4 of Annex VI - both refer to "identification of (the) EEE": "1. No ... (unique identification of the EEE)"; "4. Object of the declaration (identification of EEE allowing traceability. It may include a photograph, where appropriate)". How should item 1 and item 4 be interpreted?

Item 1 should relate to the unique identification of the DoC itself, whereas item 4 should relate to the identification of the EEE (for example by referencing the product/model number or by including a photograph).

This interpretation is consistent with the European Standard EN ISO/IEC 17050-1 (which formed the basis for the DoC layout in the NLF).

Q9.10 In terms of CE marking, is "finished product" (Article 7 (c)) and "finished EEE" (Article 15 (1)) the same?

Yes. The Blue Guide (page 15) gives additional guidance on this and suggests that for the purposes of the directive terms such as 'electrical and electronic equipment' can be read as 'electrical and electronic product' where this aids clarity of meaning. Therefore, for the purposes of Article 7 and Article 15 the terms product and EEE should be considered to have the same meaning and be interchangeable.

Q9.11 If RoHS 2 applies to a whole product, should I prepare a DoC and CE related technical documentation for the non-EEE part?

The DoC should reference the product as placed on the market under Article 4. This would normally be the model number or similar description of the whole product as placed on the market.

RoHS 2 applies to the equipment and all its constituent parts including tools, containers, cases etc. However, RoHS 2 does not apply to any manuals, documentation, consumables etc. that do not have an equipment constituent as well as any packaging intended to be discarded soon after putting the equipment into service. Technical documentation required by Article 7(b) should include compliance information on all parts of the product as described above.

Q9.12 How can Harmonised Standards be used to demonstrate compliance?

The Blue Guide (4.3, page 29) gives guidance on the presumption of conformity including the use of harmonised standards.

Q9.13 What does a CE mark on EEE mean with regard to the restricted substances?

CE marking symbolises the conformity of the product with the applicable EU requirements imposed on the manufacturer. The CE marking affixed to a product therefore is a declaration by the person responsible that

- the product conforms to all applicable EU provisions, and
- the appropriate conformity assessment procedures have been carried out.

From 2nd January 2013 EEE in scope that bears a CE marking is presumed to be in conformity with the requirements of RoHS 2 and therefore is presumed not to contain more than the tolerated maximum concentration values as mentioned in Annexes II, III and IV of RoHS 2. From 2nd January 2013, CE marking shall be the **only** marking which attests the conformity of the product with the requirements of RoHS 2.

Q9.14 Considering the time span between a product being placed on the market and being examined by a distributor, when does the product need to be in compliance with this directive?

The product needs to be compliant with the requirements that are applicable at the time of its 'placing on the market' (by the manufacturer or importer). It can thereafter continue to be made available by economic operators in the distribution chain. However, this does not refer to the end of the Article 2(2) grace period for non-compliant products; see Q2.1.

Q9.15 What are the product marking requirements for traceability reasons?

Article 7(g) requires manufacturers to mark equipment with type, batch or serial number or other element allowing its identification. The frequency of marking, whether it is for a product line, batch or individual serial numbers is a matter for business decision. Where identified non-conformities require action on the part of economic operators, product identification may be used to establish the action required to mitigate that non-conformity and to discriminate between compliant and non-compliant EEE on the market.

10. Substance Restrictions and Exemptions

Q10.1 What is the difference between RoHS 1 and RoHS 2 regarding requirements for exemption?

Several changes with regard to the requirements for exemptions in RoHS 2 have been introduced. These changes are related to procedural aspects as well as the criteria for assessing applications for exemptions. The new procedural aspects are:

- Manufacturers who apply for exemptions have to comply with the minimum requirements in Annex V.
- Deadlines for the Commission for granting, renewing or revoking an exemption are set. Furthermore deadlines for manufacturers for the application for renewal of an exemption are set.
- Transitional measures in case exemptions are not renewed or revoked are defined.

In addition to the two criteria for the assessment of exemptions in RoHS 1 (i.e. practicability, and whether the environmental, health and consumer safety impacts of substitution are negative compared to the use of the restricted substances), a third criterion has been added under RoHS 2. Hence, in the future it also has to be assessed whether the **reliability of the substitutes is ensured**. An exemption can only be granted if at least one of the three criteria justifies the specific use of a restricted substance. Please note that the impact criterion has changed from RoHS 1

to RoHS 2. With RoHS 2, if the overall impact of substituting a restricted substance were negative, this would then justify its exemption.

Additionally, the following parameters have to be taken into account:

- availability of substitutes (new)
- socio-economic impact of substitution (new)

This means that an exemption cannot be based on these parameters only. These are not considered to be as significant as the three criteria mentioned above. If a criterion is fulfilled, the parameters may subsequently influence the decision-making.

With regard to applications for exemptions, these may be submitted by a manufacturer, authorised representative of a manufacturer, or any economic operator in the supply chain as before. Furthermore the maximum exemption duration has been changed (see Q10.4) and is now to be decided on a case-by-case basis.

Exemptions are listed in two annexes in RoHS 2:

- Annex III: applications exempted from the restrictions on substances, concerning all EEE falling into the scope (including medical devices and monitoring and control instruments)
- Annex IV: applications exempted from the restrictions on substances, specific to medical devices and monitoring and control instruments

Exemptions are now granted for a maximum validity period, and may be renewed only on request (application for renewal) after a case-by-case assessment.

RoHS 2 Exemptions – maximum validity periods				
Exemptions EEE categories	Exemptions listed in Annex III		Exemptions listed in Annex IV	
	Expiry date specified	No expiry date specified	Expiry date specified	No expiry date specified
Categories 1 to 7 and 10	22 July 2011 – specified date	22 July 2011 – 21 July 2016	Not applicable	Not applicable
Categories 8 and 9 general	22 July 2014 – specified date	22 July 2014 – 21 July 2021	22 July 2014 – specified date	22 July 2014 – 21 July 2021
Category 8 in vitro*	22 July 2016 – specified date	22 July 2016 – 21 July 2023	22 July 2016 – specified date	22 July 2016 – 21 July 2023
Category 9 industrial*	22 July 2017 – specified date	22 July 2017 – 21 July 2024	22 July 2017 – specified date	22 July 2017 – 21 July 2024

* Information about the specified use of exemptions (category 8 in vitro or category 9 industrial) shall be found in the documentation accompanying an application for exemption.

Exemptions listed on annex III and IV will no longer be generally applicable when:

- Their validity period has expired;

- They are revoked because the conditions set out in article 5(1)(a) are no longer fulfilled (anyone can apply for revocation assuming they have documentation that can justify it).

Q10.2 Are exemptions granted per company, equipment or application?

Exemptions are granted for specific applications and not for the whole EEE, nor for a company. Therefore, whoever uses the substances in the specific application can benefit from the exemption.

Q10.3 Is it possible to check if an exemption has been applied for?

Yes. All information on applications for exemptions from requirements in RoHS 2 can be found at

http://ec.europa.eu/environment/waste/rohs_eee/events_rohs1_en.htm.

Q10.4 How will recent exemptions granted under RoHS 1 apply to RoHS 2?

The recent exemptions granted under RoHS 1 in 2011/534/EU¹⁹ apply until 3 January 2013 but still need to be legally incorporated under RoHS 2 in order to apply afterwards.

Q10.5 Does the exclusion granted by Article 4(4)(f) apply to all expired exemptions, irrespective of whether or not the text in Annex III or IV explicitly confirms this point?

No. It has to be explicitly confirmed in the text of the exemption that it applies to cables and spare parts mentioned in article 4(4).

For example in Annex III, no. 11a: this exemption may be used in spare parts for all EEE placed on the market before 24 September 2010, as long as this EEE is on the market. Another example is Annex III, no. 36: This application cannot be used in either EEE or spare parts after the expiry date.

Q10.6 What are the maximum concentration values for the restricted substances, and how do I make sure that my EEE complies?

The maximum concentration values referred in Article 4(2) are listed in Annex II to RoHS 2. For lead, mercury, hexavalent chromium, polybrominated biphenyls (PBBs) and polybrominated diphenyl ethers (PBDEs), the maximum concentration is 0.1 % by weight in all homogeneous materials in the EEE. For cadmium, the corresponding maximum concentration is 0.01 % by weight in all homogeneous materials in the EEE.

The harmonised standard²⁰ FprEN 50581 specifies the technical documentation the manufacturer needs to compile in order to demonstrate compliance with the substance restrictions in RoHS 2. FprEN 50581 is also the standard referred to in Article 16(2). As specified in Article 7(b), the technical documentation shall also comply with Module A in Annex II to Decision 768/2008/EC. The standard should therefore be read in conjunction with Module A.

¹⁹ COMMISSION DECISION of 8 September 2011 amending, for the purposes of adapting to technical progress, the Annex to Directive 2002/95/EC of the European Parliament and of the Council as regards exemptions for applications containing lead or cadmium.

²⁰ "Unanimous vote in favour under "Unique Acceptance Procedure"; 9 June 2012. This paragraph will be amended when the standard is finished and published.

As indicated by Article 16(2), Member States shall presume that EEE assessed according to the harmonised standard complies with the requirements of RoHS 2. However, Member States may still carry out analysis of such EEE as part of their enforcement activities. If such analysis shows a violation of the substance restrictions, the manufacturer of the EEE bears the full responsibility for this despite having assessed the EEE according to the standard.

Q10.7 Do the substance restrictions apply to the production process?

No. The restrictions only apply to finished EEE. The restricted substances may therefore be used in the production process, as long as they do not violate other regulations and the finished EEE does not contain the substance above the maximum concentration values.

Q10.8 What is a homogeneous material?

A homogeneous material is either:

- 1) A material with a uniform composition throughout; or
- 2) A material that consists of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding or abrasive processes.

Examples of homogeneous materials include a plastic cover to a computer screen, a copper wire inside a cable, and a solder.

Almost all EEE consist of many different homogeneous materials. A semiconductor package, for instance, contains plastic moulding material, a lead frame alloy, tin electroplating coatings on that frame, and gold bonding wires. All of these are separate homogeneous materials, and the maximum concentrations are therefore applied to each of the materials **individually**.

Any sample taken from EEE by a Member State enforcement authority should not contain the restricted substances above the maximum concentrations unless there is an applicable exemption. Therefore due care and risk considerations should be taken when homogenising samples for compliance demonstration purposes where such homogenisation may dilute the presence of the restricted substances.

Q10.9 What is “closed-loop”?

Under Article 4(5), spare parts recovered from EEE placed on the market before RoHS 1 entered into force on 1 July 2006, and reused in new EEE placed on the market before 1 July 2016, are exempt from the substance restriction provided that their reuse takes place in an “auditable closed-loop business-to-business return system”. This means that spare parts containing the restricted hazardous substances at levels above the maximum concentration may only be resold to other businesses and only within a system where all transfers are registered, documented and tracked. (That is, it should not be sold on the “regular market”) Furthermore, both the buyer and the end user should be informed about the reuse of parts, including the risk of hazardous substance content. This could for example be indicated on the packaging.