ORGALIME

# ORGALIME RoHS GUIDE

## A practical Guide to understanding the specific obligations of

recast Directive 2011/65/EU
on the Restriction of the Use of Certain Hazardous Substances in EEE
(RoHS II)

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The European Engineering Industries Association

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# FOREWORD

Directive 2002/95/EC on the Restriction of Use of Certain Hazardous Substances in Electrical and Electronic Equipment (known as the "RoHS Directive" or "RoHS I") restricts the use of lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyls and polybrominated diphenylethers in certain electrical and electronic equipment since 1 July 2006.

In December 2008, the European Commission proposed to recast Directive 2002/95/EC.
The result of this recast is Directive 2011/65/EU (hereafter referred to as the "recast RoHS Directive" or "RoHS II"), which was finally adopted on 27 May 2011. The recast RoHS Directive has been published in the Official Journal of the EU on 1 July 2011 and entered into force on 21 July 2011. Member States will have to transpose the recast RoHS Directive into national law by 2 January 2013 at the latest.

The initial RoHS Directive 2002/95/EC and its successive amendments[1] will be repealed with effect from 3 January 2013. Notwithstanding other EU legislation and Regulation (EC) 1907/2006 (REACH) in particular, as of its entry into force, the recast RoHS Directive is a critical reference for hazardous substance restrictions in electrical and electronic equipment.

The purpose of this ORGALIME Guide is to explain the main changes and obligations arising from the recast, and to identify their consequences for ORGALIME industries. Its update of September 2012 provides to readers the common understanding of the Directive of the affected European manufacturers of electrical and electronic equipment in the context of the Commission's consultation on the draft RoHS2-FAQ Guidance Document of 15 June 2012 and its announced possible revision before 3 January 2013.[2]
These conclusions reflect the best knowledge of industry experts across Europe and the state of the art at the moment of its publication. This Guide will be regularly updated to accommodate latest developments. To ensure that your copy is up to date, please register on Orgalime's website http://publications.orgalime.org.

The principles contained in this Guide are however not legally binding, and following it gives no guarantees. Producers must ultimately exercise their own judgement. A binding interpretation of Community legislation is the exclusive competence of the European Court of Justice. ORGALIME also recommends to producers, when using this Guide, to always refer to the national legislation, and guidance if any, of the Member State they are dealing with.

This ORGALIME Guide is to be considered as complementary to other ORGALIME Guides on the WEEE and RoHS Directives.[3] Until repeal of the initial RoHS Directive 2002/95/EC, with effect from 3 January 2013 these other Orgalime Guides remain valid and should be consulted in parallel.
In addition, ORGALIME has also published a Guide on the REACH Regulation[4], which provides further complementary information to this Guide.

ORGALIME, the European Engineering Industries Association, speaks for 37 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 22 European countries. The industry employs some 10.2 million people in the EU and in 2011 accounted for some €1, 666 billion of annual output. The industry not only represents some 28% of the output of manufactured products but also a third of the manufactured exports of the European Union. This guide has been drafted in collaboration with the European Sector Associations which are listed hereafter in Annex E.

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[1] Commission Decisions 2005/618/EC, 2005/717/EC, 2005/747/EC, 2006/310/EC, 2006/690/EC, 2006/291/EC, 2006/692/EC, 2008/385/EC, 2009/428/EC, 2009/443/EC, 2010/122/EU and 2010/571/EU.
[2] See http://ec.europa.eu/environment/waste/rohs_eee/events_rohs3_en.htm.
[3] "A practical Guide to understanding the EC Directives on Waste Electrical and Electronic Equipment (WEEE) and on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) of 27 January 2003", published in April 2003; ORGALIME GUIDE " A practical Guide to understanding the scope of Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) and Directive 2002/95/EC on the Restriction of the Use of Certain Hazardous Substances in EEE (RoHS) of January 2006; "ORGALIME Guide to contractual options for producers selling business-to-business equipment - Contract Clauses for WEEE Obligations" (March 2006) available for download free of charge at: http://publications.orgalime.org.
[4] ORGALIME GUIDE "A practical guide for downstream users, article producers and article importers to understanding Regulation No 1907/2006 on the Registration, Evaluation and Authorisation of Chemicals (REACH)", published in May 2007 available for download free of charge at: http://publications.orgalime.org.

# 1. CONTENTS OF THE RECAST ROHS DIRECTIVE

## 1.1. PURPOSE OF THE DIRECTIVE[5]

Directive 2002/95/EC restricts the use of lead, cadmium, hexavalent chromium, mercury and polybrominated biphenyls (PBB) and polybrominated diphenylethers (PBDE) for electrical and electronic equipment put on the market since 1 July 2006.[6]

The recast RoHS Directive maintains these restrictions and extends them to medical devices (Category 8) and monitoring and control instruments (Category 9). The recast also introduces a new scope Category 11 that includes all electrical and electronic equipment (EEE) not covered by any of the other 10 categories in the scope of the recast RoHS Directive after a period of 8 years. In addition, the recast RoHS Directive establishes a methodology for reviewing the existing six substance restrictions and for introducing new restrictions.

The recast RoHS Directive is based on Article 114 of the Treaty on the Functioning of the European Union (Lisbon Treaty)[7] and therefore aims at harmonising the legislation of Member States in the area of restricting the use of certain hazardous substances in electrical and electronic equipment (EEE).

Annexes III and IV of the recast RoHS Directive list applications, which are exempted from the requirements of the Directive for a certain time period. These Annexes of the recast RoHS Directive are subject to adaptation to scientific and technical progress under the so-called Comitology procedure (see Chapters 1.6 and 3 of this Guide). Applications for exemptions, deletions of exemptions and renewals of exemptions need to respect the contents provided for in Annex V of the recast RoHS Directive and a standardised application format for exemptions to be adopted by the Commission under Comitology will apply in the future.

## 1.2. OVERVIEW OF MAIN CHANGES INTRODUCED BY THE RECAST

The recast addressed the following issues and introduces the following main changes and/or new provisions in comparison to the initial RoHS Directive 2002/95/EC:

| ISSUE | MAIN CHANGES AND/OR NEW PROVISION |
|---|---|
| **SCOPE (Article 2, Article 3, Annex I)** | • Removal of reference to Annex I.A of Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE), which provides for categories in the scope; replaced by the introduction of a new Annex I of the recast RoHS Directive listing 11 scope categories directly – consequently, there is no longer a link between the WEEE and the (recast) RoHS Directive.<br>• Extension of the scope to medical devices and monitoring and control instruments which are placed on the market from 22 July 2014, to in vitro diagnostic medical devices which are placed on the market from 22 July 2016, and to industrial monitoring and control instruments which are placed on the market from 22 July 2017 via the new Annex I.<br>• Introduction of a new scope Category 11 in Annex I to cover all electrical and electronic equipment that is not already covered by the other categories by 22 July 2019 (so-called “open scope” unless a scope exclusion applies).<br>• A derogation clause for Member States to provide that EEE that was outside |

[5] See also ORGALIME Guide “A practical guide for downstream users, article producers and article importers to understanding Regulation No 1907/2006 on the Registration, Evaluation and Authorisation of Chemicals (REACH)”, published in May 2007.
[6] Please note: Some of these substances are also restricted by other EU legislation, such as REACH (Regulation (EC) No 1907/2006).
[7] Corresponding to Article 95 of EC Treaty before the entry into force of the Lisbon Treaty.

| | |
|---|---|
| | the scope of Directive 2002/95/EC but is now inside the scope of the recast RoHS Directive may continue to be made available on the market[8] until 22 July 2019. Therefore, any product newly in scope benefits from the transitional period of Article 2(2). This includes any product new in scope falling in any of the 11 categories of Annex I.[9]<br>• A new definition of "electrical and electronic equipment (EEE)" in Article 3(a)): "*EEE means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1000 volts for alternating current and 1500 volts for direct current.*"<br>• A set of modified and new scope exclusions in Article 2, including exclusions for large-scale stationary industrial tools and large-scale fixed installations, as well as means of transport, non-road mobile machinery for professional use or certain photovoltaic panels and R&D equipment.<br>• The obligation on the Commission to review the need to amend the scope/scope exclusions of the recast RoHS Directive and to present a report and, if appropriate, a legislative proposal by 22 July 2014 – the ordinary legislative procedure applies for this review. |
| **SUBSTANCE RESTRICTIONS (Article 4 and 6, Annex II)** | • The list of restricted substances has been moved from Article 4 to a new Annex II (content wise, the restricted substances remain the same as in Directive 2002/95/EC, i.e.: lead, cadmium, hexavalent chromium, mercury and polybrominated biphenyls (PBB) and polybrominated diphenylethers (PBDE)).<br>• The Annex II list of restricted substance shall be amended by the Commission in application of a newly established methodology (see new Article 6, and Chapter 1.6 of this Guide) and the new Comitology procedure (see Chapter 3 of this Guide) – a first review of Annex II shall take place by 22 July 2014 at the latest and periodically thereafter. The Commission has to consult stakeholders before amending Annex II and any review and amendment of Annex II must be coherent with Regulation 1907/2006 (REACH).<br>• Annex II also specifies the tolerated maximum concentration values (MCVs) expressed as a percentage of the weight of the homogeneous materials for restricted substances[10] - "homogeneous material" is defined in Article 3 and the Commission shall adopt detailed rules for compliance with these MCVs via Comitology.<br>• The risks arising from the use of HBCDD, DEHP, BBP and DBP shall be considered as a priority, and any substances of small size or internal or surface structure (nanomaterials) should be examined as soon as scientific evidence is available and taking into account the precautionary principle. |
| **EXEMPTIONS (Article 5, Annexes III, IV, V and VII)** | • Annex III contains a list of applications exempted from the substance restrictions regarding all electrical and electronic equipment (Categories 1 to 11).[11]<br>• Annex IV contains a list of applications exempted from the restrictions specific to medical devices and monitoring and control instruments |

[8] The impact of the term "made available on the market" in Article 2(2) has been subject of an impact assessment under the responsibility of DG Environment of the European Commission (BioIS RoHS 2 scope impact assessment study, see http://rohs.bios.com), which identified the need to revisit Article 2(2). The Commission's related decision on a possible amendment of the Directive in this respect is currently pending. ORGALIME´s contribution to the BioIS´s study is available under http://www.orgalime.org/positions/positions.asp?id=446.

[9] The relationship between Article 2(2) and Article 4(3) & 4(4) is currently under investigation. BioIS Final Report suggests two possible options (see http://rohs.bios.com).

[10] Commission decision 2005/618/EC will be repealed with effect from 3 January 2013, since directly incorporated into Annex II of the recast RoHS Directive.

[11] Commission Decisions 2005/717/EC, 2005/747/EC, 2006/310/EC, 2006/690/EC, 2006/291/EC, 2006/692/EC, 2008/35/EC, 2008/385/EC, 2009/428/EC, 2009/443/EC, 2010/122/EU and 2010/571/EU will be repealed with effect from 3 January 2013, since directly integrated in the recast RoHS Directive.

| | |
|---|---|
| | (Categories 8 and 9).<br>• Annexes III and IV shall be adapted to scientific and technical progress by the Commission via Comitology according to redefined criteria, including the availability and reliability of substitutes, a life cycle perspective on the environmental; health and safety benefits and impacts or the socio-economic impact of the exemption.<br>• Annex V introduces the minimum standards for applications for exemptions, deletions or renewals of exemptions – the Commission shall adopt a harmonised format for applications via Comitology and provide for comprehensive guidance.<br>• Applications have to be filed within 18 months preceding the expiration date of an exemption.<br>• Introduction of a better-structured procedure for the process of granting exemptions, including stakeholder consultation, a deadline of 15 days for the Commission to acknowledge receipt of an application, the obligation for the Commission to decide on applications for renewal no later than 6 months before expiry of the exemption or the obligation on it to make a summary of the application publically available.<br>• Validity periods are determined case by case for individual exemptions: the maximum validity period for EEE exemptions for Categories 1 to 7, 10 and 11 is five years and for Categories 8 and 9 seven years.<br>• Introduction of a transition period of minimum 12 and maximum 18 months in the event that the exemption is deleted or its renewal is rejected. |
| **ALIGNMENT WITH NEW LEGISLATIVE FRAMEWORK (NLF)** | • The recast RoHS Directive contains formal requirements regarding CE marking, conformity assessment and other obligations of economic operators based on the so-called "New Legislative Framework" (NLF) consisting of Regulation (EC) 765/2008 and Decision 768/2008/EC.<br>• Conformity assessment is to be carried out as "Internal Production Control" under the sole responsibility of the manufacturer.<br>• Annex VI of the recast RoHS Directive establishes particular requirements on the Declaration of Conformity (DoC).<br>• Article 16 of the recast RoHS Directive introduces the presumption of conformity for EEE that complies with harmonised standards listed in the Official Journal of the EU.<br>• Several provisions regarding corrective measures (i.e.: recall or withdrawal) in case of non-compliance have been introduced.<br>• The recast RoHS Directive includes a number of new NLF-relevant definitions provided for in Decision 768/2008/EC, such as “economic operator”, “making available on the market”, “placing on the market”, “harmonised standard”, “technical specification”, “recall” or “withdrawal”. |
| **TERMS AND DEFINITIONS (Article 3)** | • Introduction of several scope-related definitions, including definitions of “non-road mobile machinery made available exclusively for professional use”, “large scale stationary industrial tools”, “large scale fixed installations”, “cables” and “spare parts”.<br>• Introduction of a definition of “homogeneous material”.<br>• Introduction of definitions on the criteria for granting exemptions, such as “availability of a substitute”, “reliability of a substitute”.<br>• Introduction of new definitions related to the alignment of the RoHS Directive with the New Legislative Framework, such as “economic operator”, “making available on the market”, “placing on the market”, “harmonised standard”, “technical specification”, “recall” or “withdrawal”. |
| **REVIEW (Article 24)** | • In addition to the review of the scope/scope exclusions by 22 July 2014, there shall be a general review of the recast RoHS Directive no later than 22 July 2021. |

| | |
|---|---|
| **TRANSPOSITION (Article 25)** | • Member States shall transpose the recast RoHS Directive into national legislation by 2 January 2013. |
| **COMITOLOGY (Article 19-22)** | • The Comitology procedure has been modified by the Treaty of Lisbon, which establishes two types of Comitology decisions, namely "delegated acts" (Article 290) and "implementing acts" (Article 291)<br>• Under the recast RoHS Directive:<br>  ○ Article 290 is the legal base for future Commission decisions on amendments to Annex II, detailed rules for complying with maximum concentration values, and the adaptation to technical and scientific progress of Annexes III and IV.<br>  ○ Article 291 is the legal base for Commission decisions for developing the application format for exemptions of Annex V and for related guidance. |
| **STAKEHOLDER CONSULTATION (Article 5(7) and 6(1))** | • The Commission has to consult stakeholders in the conduct of:<br>  ○ reviewing existing restrictions (Article 6(1));<br>  ○ setting new restrictions (Article 6(1));<br>  ○ deciding on the level of tolerated maximum concentration values (Article 6(1)) and<br>  ○ deciding on exemptions (Article 5(7)). |

## 1.3. SCOPE

### 1.3.1. Introduction

To understand the scope of the RoHS II Directive, namely which products are subject to the RoHS provisions, it is fundamental to develop a common understanding of the scope provisions, which must be fully in line with the legal text and spirit of RoHS II and the NLF:

- RoHS II is a standalone Directive. There is no longer a link to the Directive on Waste Electrical and Electronic Equipment 2002/96/EC (WEEE). Until the repeal of the initial RoHS Directive 2002/95/EC, a product that does not fall under the scope of the WEEE Directive is automatically excluded from the scope of RoHS. Following the repeal of Directive 2002/95/EC, this will no longer be the case;

- Many definitions have been changed and new definitions have been added;

- Some definitions that were previously included in the FAQ document, published by the European Commission in 2006, are now in the legal text but with different wording and meaning. **Products that were excluded from the RoHS Directive because they did not fall within the WEEE scope or were excluded by some specific criteria or definition should now be reassessed under the new definitions and criteria;**

- The compliance obligations, including the substance restrictions and the new NLF obligations, arise for manufacturers and importers of EEE. Distributors bear verification requirements;

- The definition of "electrical and electronic equipment (EEE)" cannot be interpreted as targeting anything and everything with the slightest connection to electricity or electronics, but requires an assessment of the entire definition of "EEE" (see hereafter).

Keeping this in mind, the following considerations illustrate the system of the scope provisions of the RoHS II Directive.

## 1.3.2. EEE definition

The recast RoHS Directive applies only to products that represent a functional unit that is a finished EEE[12] meeting the definition of "electrical and electronic equipment - EEE" provided in Article 3(1):

> ***Article 3(1)***
> *"electrical and electronic equipment" or EEE means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1000 volts for alternating current and 1500 volts for direct current;*

As indicated above, "equipment" can only be a unit with a function in itself. A confirmation of this understanding is provided in Article 3(27) of the recast RoHS Directive, where a "spare part" is defined as follows:

> ***Article 3(27)***
> *a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part.*

This means implicitly that "equipment" can only be a unit with a function in itself, but not a (spare) part or component, which according to Article 3(27) is something which is below the level of "equipment".

RoHS II does not stipulate more precisely the term "equipment". However, to get a common understanding of the RoHS II scope provisions and to make a judgment whether a relevant product has to comply with the RoHS obligations, the definition of "equipment" within the IEC International Electrotechnical Vocabulary 60050 is helpful:

> *a single apparatus or set of devices or apparatuses, or the set of main devices of an installation, or all devices necessary to perform a specific task*

The IEC International Electrotechnical Vocabulary 60050 also defines "apparatus", i.e.: as follows:

> *device or assembly of devices which can be used as an independent unit for specific functions*

As described above, the concept of RoHS II and its category approach (see also Chapter 1.3.2) of "functional units", is coherent with the definition of "equipment" provided by the IEC International Electrotechnical Vocabulary 60050.

In this sense, single components and parts of finished products are not in the scope of the recast RoHS Directive. For further details please see Chapter 1.3.7.

Furthermore, RoHS II defines in Article 3(2) the term "dependent":

> ***Article 3(2)***
> *for the purposes of point 1, "dependent" means, with regard to EEE, needing electric currents or electromagnetic fields to fulfil at least one intended function.*

The definition of "dependent" provided by the RoHS recast differs significantly from the definition endorsed by the Commission in the FAQ document[13] regarding RoHS I. In this document "dependent" refers to the intended function of an EEE. All products excluded by the former definition should be reassessed against this new definition.

[12] Article 15(1) refers to the functional unit as "finished EEE": "The CE marking shall be affixed visibly, legibly and indelibly to the finished EEE or to its data plate […]"
[13] See also Frequently Asked Questions on Directive 2002/95/EC and Directive 2002/96/EC of May 2005, page 4.

In this context, Recital 12 of RoHS II states that the "intended functions" are to be determined on the basis of objective characteristics, such as the design of the product and its marketing, meaning that "ex-post" criteria (such as the physical size, weight or volume of an installation for which the EEE is destined) that can be verified only after the placing of the market of the equipment in question, are not suitable for determining the scope.

Whether or not a certain function represents an "*intended function*" as required by the given definition needs to be assessed case by case based on the explicit process(es) or action(s) for which the product has been designed for. Where standards exist they can in our view provide guidance for "*intended function*" of the product, and producer manuals, instructions, and websites can be other means to identify the intended function of a product.
If electrical energy is used only for startup functions, this type of equipment is in our view not covered by Directive 2011/65/EU.

Moreover, Recital 12 of the recast RoHS Directive states that the definition of "*dependent*" is to "*complement*" the definition of EEE, however, it is not supposed to overrule or go beyond the definition of "EEE", which would result from considering the term "dependent" the only relevant criterion for assessing whether or not an equipment represent an EEE under RoHS II.
Instead, all criteria of the definition of "EEE" given in Article 3(1) need to be assessed in order for the manufacturer to conclude if his equipment represents an EEE under RoHS II or not. This includes in particular also an assessment of the notion "dependent *in order to work properly*".

**Summary of RoHS2 Scope Decision Flow Chart:**

| | |
|---|---|
| Components, parts, and items other than functional units | Not in scope in their own right, see Chapter 1.3.7 |
| ⇩ | |
| **EQUIPMENT**<br>(in the meaning of IEC International Electrotechnical Vocabulary 60050) | **LEVEL AT WHICH RoHS2 SUBSTANCE RESTRICTIONS & CE MARKING OBLIGATIONS ARISE:**<br>1. Does my equipment fall into one of the categories of annex I?<br>2. Does my equipment meet definition of Articles 3(1) and 3(2)?<br>3. Does the Directive not apply following Article 2(4)? I.e.: Is my EEE/its application explicitly excluded?<br>4. If not explicitly excluded:<br>a. Do the material restrictions apply?<br>b. Does an exemption apply? |
| ⇩ | |
| Large scale stationary industrial tools (LSSIT) | Not in scope according to Article 2(4)(d); see Chapter 1.3.5 |
| ⇩ | |
| Large scale fixed installations (LSFI) | Not in scope according to Article 2(4)(e); see Chapter 1.3.5 |

## 1.3.3. Category approach

The scope of the recast RoHS Directive is defined in Article 2 as follows:

> ***Article 2***
> *1. This Directive shall, subject to paragraph 2, apply to EEE falling within the categories set out in Annex I.*
> *2. 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.*
> *3. This Directive shall apply without prejudice to the requirements of Union legislation on safety and health, and on chemicals, in particular Regulation (EC) No 1907/2006, as well as the requirements of specific Union waste management legislation.*

According to Article 2(1), RoHS II applies to electrical and electronic equipment falling under the categories set out in Annex I:

> ***ANNEX I – Categories of electrical and electronic equipment covered by this Directive***
> *1. Large household appliances*
> *2. Small household appliances*
> *3. IT and telecommunications equipment*
> *4. Consumer equipment*
> *5. Lighting equipment*
> *6. Electrical and electronic tools (with the exception of large-scale stationary industrial tools)*
> *7. Toys, leisure and sports equipment*
> ***8. Medical devices***
> ***9. Monitoring and control instruments including industrial monitoring and control instruments***
> *10. Automatic dispensers*
> ***11. Other electrical and electronic equipment not covered by any of the categories above***

The above shown Annex I, Recital 3, Article 2(1) and Article. 5(2) of RoHS II confirm the continuation of the "category approach" of the Directive following the recast.

The initial Categories 1-10 of the Directive were established at the level of equipment that represents a functional unit in itself, e.g.: a dishwasher, however, not its individual components or parts (see also previous Chapter 1.3.2).[14]

The recast has extended this to further EEE through the introduction of a new scope Category 11 titled "other EEE not covered by any of the categories above" (so-called "open scope"). In other words: The Directive's approach of addressing equipment that represents a functional unit in itself has been extended to this new Category 11[15]. Therefore, all electrical and electronic equipment which represent a functional unit (not parts nor components) will fall into the scope as of that date unless it is explicitly excluded.

Furthermore, Article 2(2) of the recast RoHS Directive determines that any product newly in scope of RoHS II benefits from an 8 years transitional period:

> ***Article 2(2)***
> *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.*

[14] See also Frequently Asked Questions on Directive 2002/95/EC and directive 2002/96/EC of May 2005, page 6, concerning "finished product" and "direct function" definitions and components interpretation.

[15] This is explicitly supported by recital 3: "*Directive 2002/95/EC provides that the Commission shall review the provisions of that Directive, in particular, in order to include in its scope equipment which falls within certain categories and to study the need to adapt the list of restricted substances on the basis of scientific progress, taking into account the precautionary principle, as endorsed by Council Resolution of 4 December 2000.*"

The transitional period includes any product new in scope falling in any of the 11 categories shown above[16]. A clarification for this is given in the following Commission statement, issued at the occasion of the adoption of the RoHS II Directive:

> *The Commission interprets Article 2(2) as meaning that electrical and electronic equipment which was outside the scope of Directive 2002/95/EC, but which would be covered by the new Directive, does not need to comply with the requirements of this Directive during a transitional period of eight years. EEE which was outside the scope of Directive 2002/95/EC, but which would be covered by the new Directive, includes among others EEE, "cables" mentioned in Article 4 and the related definition in Article 3(5);*[17]

Besides the new scope Category 11, two more categories are added to the scope of the recast RoHS Directive:

Article 4(3) states that medical devices monitor and control instruments, in vitro diagnostic medical device and industrial monitoring and control instruments shall all be included.

> ***Article 4(3)***
> *Paragraph 1 shall apply to medical devices and monitoring and control instruments which are placed on the market from 22 July 2014, to in vitro diagnostic medical devices which are placed on the market from 22 July 2016 and to industrial monitoring and control instruments which are placed on the market from 22 July 2017.*

Medical devices are defined by Articles 3(21) & 3(22) as:

> ***Article 3(21)***
> *"medical device" means a medical device within the meaning of point (a) of Article 1(2)of Directive 93/42/EC which is also EEE;*
> ***Article 3(22)***
> *"in vitro diagnostic medical device" means in vitro diagnostic medical device within the meaning of point (b) of Article 1(2) of Directive 98/79/EC.*

Industrial monitoring and control instruments are defined by Article 3(24) as:

> ***Article 3(24)***
> *"industrial monitoring and control instruments" means monitoring and control instruments designed for exclusively industrial or professional use.*

Important note: The difference of definition of medical devices between RoHS1 (which linked up to Directive 2006/96/EC on WEEE) and RoHS2 lead to the situation today that there are some medical devices that fall under Category 8 of RoHS II and other medical devices that fall under Category 11 of RoHS II with subsequent different compliance deadlines.

The following three examples of medical equipment, which do not fall under the scope of Directive 93/42/EEC or 98/79/EC (not CE marked under either of these medical device directives), would thus not fall into RoHS2 Category 8:

- Analyzer used for screening or forensic purposes, e.g. for high-throughput DNA analysis, based on weighing DNA forensic markers, used to derive a DNA profile for an individual, but also in other areas to identify a wide range viruses or microbial contaminants;

- Interface equipment between a patients' computer and his self-testing IVD medical device, used by a patient to transfer data from his blood glucose meter to his home PC for his personal monitoring and follow up;

[16] The relationship between Article 2(2) and Articles 4(3) and 4(4) is currently under investigation. The BioIS Final Report proposes two options (see http://rohs.biois.com).
[17] Commission Statement 8117/11 ADD1 REV1

- Devices used in the veterinary area. e.g.: blood glucose meters used for pets, which may be even identical as those used for humans.

However, the Directive does not apply to equipment and products that is explicitly excluded. For further details, please consider Chapter 1.3.4.

## 1.3.4. Equipment and Non-EEE products not in scope

RoHS II recognises the following cases of equipment as not in scope because they are excluded or not–EEE:

Equipment which does not meet the definition of Article 3(1) complemented by Article 3(2), thus:

a) Equipment, which does not depend on electric current and electromagnetic fields to work properly, and equipment which is not for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1 000 volts for alternating current and 1 500 volts for direct current;

b) Any other product that does not depend on electric current and electromagnetic fields to work properly (e.g.: textiles, furniture, cable management products).

Equipment and their applications on which the Directive does not apply ("scope exclusions") according to Article 2(4) as summarised below.

This Directive does not apply to:

*Article 2(4)*

*a) equipment which is necessary for the protection of the essential interests of the security of Member States, including arms, munitions and war material intended for specifically military purposes;*
*b) equipment designed to be sent into space;*
*c) equipment which is specifically designed and to be installed as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment ;*
*d) large-scale stationary industrial tools;*
*e) large-scale fixed installations;*
*f) means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved;*
*g) non-road mobile machinery made available exclusively for professional use;*
*h) active implantable medical devices;*
*i) photovoltaic panels intended to be used in a system that is designed, assembled and installed by professionals for permanent use at a defined location to produce energy from solar light for public, commercial, industrial and residential applications;*
*j) equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis.*

❖ **"Part of another type of equipment not falling within the scope"**

Article 2(4)(c) of the recast RoHS Directive states the exclusion from the scope of:

***Article 2(4)(c)***
*Equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment.*

This exclusion means that equipment fulfilling **all** of the following requirements is excluded from the scope of the recast RoHS Directive:

- Specifically designed to be part of equipment that is itself either excluded or not in the scope;

- Is installed as part of equipment that is itself either excluded or not in the scope;
- Can only fulfil its function if it is part of equipment that is itself either excluded or not in the scope;
- Can only be replaced by equipment with the same specific design.

The same article also lists other excluded equipment:

- Large-scale stationary industrial tools;
- Large-scale fixed installations;
- Means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved;
- Non-road mobile machinery made available exclusively for professional use.

Therefore, equipment that is part of any such excluded equipment, and which fulfils all of the previously listed criteria, is also excluded from the scope of the recast RoHS Directive.

### ❖ "Large scale stationary industrial tools" and "large scale fixed installations"

Articles 3(3) and 3(4) define exclusions for "large scale stationary industrial tools - LSSIT" and "large scale fixed installations - LSFI". Further details regarding these exclusions are provided in Chapters 1.3.5 and 1.3.6.

### ❖ "Non-road-mobile machinery"

Article 3(28) of the recast RoHS Directive states:

> ***Article 3(28)***
> *"non-road mobile machinery made available exclusively for professional use" means machinery, with an on-board power source, the operation of which requires either mobility or continuous or semi-continuous movement between a succession of fixed working locations while working, and is made available exclusively for professional use.*

### ❖ Batteries and accumulators

Batteries and accumulators falling into the scope of Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators do not fall into the scope of the RoHS Directive[18]. The content of hazardous substances is regulated by the Directive 2006/66/EC, as stated in Recital 14 in combination with Article 2(3).

### ❖ Active implantable medical devices

Article 3(23) of the RoHS Directive states:

> ***Article 3(23)***
> *"active implantable medical device" means any active implantable medical device within the meaning of point (c) of Article 1(2) of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.*

Medical devices designed for being implanted in the human body are excluded from the scope of the recast RoHS Directive.

### ❖ Means of transport

Article 2(4)(b) excludes "means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved".
Examples of products benefiting from this exclusion are vehicles and boats.

[18] Recital 14 of the recast RoHS Directive states, that the Directive should apply without prejudice to Union legislation on safety and health requirements and specific Union waste management legislation, in particular 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 Regulation (EC) No 850/2004.

## 1.3.5. Large scale fixed installations (LSFI) and large scale stationary industrial tools (LSSIT)

Articles 3(3) and 3(4) of the recast RoHS Directive define exclusions for “large scale stationary industrial tools - LSIT” and “large scale fixed installations - LSFI“.

Notwithstanding some potential overlap of the exclusions of LSFI and LSSIT, these two cases of scope exclusions are in general different, including in terms of the physical size, weight and volume of the equipment falling under them (see RoHS Decision trees for LSFI on page 17 and for LSSIT on page 18).

Some (interpretative) criteria may fit both (e.g.: permanently installed and de-installed by professionals), while some may not (e.g.: a quantitative figure of physical size, weight, volume of “large scale”). Certain distinctions will therefore have to be made.

In both cases, the term “large-scale”:

- Does not stand on its own, but needs to be understood in its entire context of the full legal definition;
- Cannot be determined or enforced by “ex-post” criteria (i.e.: criteria that relate to after the placing on the market of equipment going into LSFI/LSSIT), such as the criterion of physical size of the installation in terms of a precise quantitative figure of size, weight or volume of an installed or dismantled installation;
- Instead, needs to be understood in terms of the complexity and customized application and interdependency of the equipment /components/machines in question. However, it is important to note that the level and degree of complexity and interdependence will in general be different between LSSIT and LSFI;
- Is (as all other elements of the definition of LSFI/LSSIT) a case by case decision, up to the manufacturer of the equipment to assess and prove to control authorities.

However to distinguish the difference, LSSIT should be understood as assembly of machines, devices, and/or components to be applied for certain application in an industrial environment, such as “machine tools”.

Buildings and sites, chemical plants do not meet the definition of EEE under RoHS II, however, they may comprise various contiguous subsystems that represent EEE under RoHS II and that EEE manufacturers/importers need to assess with respect to Article 2(4).
Subsequent actors in the supply chain bear the responsibility of verifying the technical documentation and the presence of the CE marking on the EEE/apparatus that are IN the scope of RoHS II. However, they have rightly not been given responsibilities on the substance content of equipment that has already been designed, manufactured and placed on the market before the EEE was supplied to them.

Semi-mobile machinery (e.g.: running on rails) can be considered as permanent use, on the other hand, machinery that is used on different sites during its life time is not considered as permanent. The fact that equipment is readily displaced to another location or that it is intended for use at one single location during its life time provides a clear indication.

### ❖ Large scale fixed installations (LSFI)

Article 3(4) defines “large scale fixed installation - LSFI“ as follows:

***Article 3(4)***
*“large scale fixed installation” means*
- *a large scale combination of*
- *several types of apparatus and, where applicable, other devices, which are*
- *assembled and installed by professionals and*
- *intended to be used permanently in a*
- *pre-defined and dedicated location, and to be de-installed by professionals.*

Following Article 3(4), only equipment which fulfils all the following conditions is excluded:

- It should be a large-scale combination of several types of apparatus and, where applicable, other devices;

- They are assembled, installed and de-installed by professionals;

- They are intended to be used permanently in a pre-defined and dedicated location (i.e.: when used, they are not to be removed from the dedicated location of the building or the structure where they are installed/they are integrated to, but during the use phase permanently incorporated into that location). (Note: the previous criterion indicates that also this equipment can be de-installed during another phase than the use phase, e.g.: relocation of an industrial site).

The common understanding of these scope exclusions should be based on the complexity of the combination as the core indicator for “large scale combination” in the context of the entire definition, rather than a certain size, weight, or volume definition, which always risks being arbitrary and not in accordance with the legal definition.

The following terms in the context of the scope exclusion of “large scale fixed installation” should be based on the understanding of the NLF as follows:

- “Large scale” in the context of the scope exclusion of “large scale fixed installation” means “a combination of several apparatus and devices, where the combination is not intended to be placed on the market as a single commercial or functional unit and which is different from standalone consumer products due to, for example, lifespan, number of produced units or custom tailor-made characteristics of the combination, interdependency of the different apparatus/devices/subassemblies/sub-installations of the combination”.
  Recital 12 states that the "intended functions" are to be determined on the basis of objective characteristics, such as the design of the product and its marketing”, meaning that "ex-post" criteria (such as the physical size, weight or volume of an installation the EEE is determined for) that can be verified only after the placing of the market of the equipment in question, are not suitable for determining the scope.

- “Apparatus” means “any device or unit of equipment that has a direct function, its own enclosure and, if applicable, ports and connections intended for end users”. Direct function means “any function of a component or a finished product which fulfils the intended use specified by the manufacturer in the instructions for use for an end user”. (These definitions are provided in the existing FAQ on Directive 2002/95/EC and tie in with the IEC International Electrotechnical Vocabulary 60050. Alternatively, the IEC definitions could be used directly).

- **Interdependency particularly includes the following three cases:**
  - Interdependency of apparatus and other devices: The installation is composed of apparatus and devices working together to fulfil one or more of the intended functions of the installation (e.g.: airport luggage system);
  - Interdependency of “sub-systems”: The installation is composed of different systems performing different functions but concurring to the fulfilment of one or more of the intended functions of the installation. (e.g.: production line providing cutting, painting and packaging);
  - Interdependency of different installations: The installation is composed of different inter-dependent installations performing different functions essential to the fulfilment of the installation intended function (e.g.: production line together with ventilation, air conditioning, gas extraction, water closed cycle purification, exhaust gas treatment, etc.).

- “Permanent use” means “permanently incorporated into the location during the use phase, not intended to be moved from the location to another during that phase”. The installation has been designed and installed to be used in the location for its entire life time.

However:

- This does not mean that it would not be possible to relocate (the definition of the exclusion indicates itself that also this equipment can be de-installed during another phase than the use phase, e.g.: relocation of an industrial site); it would normally not be the intention to relocate and normally require some level of modification, e.g.: at end of life stage, apparatus will have to be relocated for waste management;

- The term "fixed" should not be mixed with "not moveable", as the term "fixed" in the context of large scale fixed installation still allows that the equipment contains moveable parts;

- Equipment with limited movement, perhaps mounted on rails to allow limited traverse, would still be considered "fixed".

- "Location" includes "industrial, commercial and residential locations, such as industrial sites, hospitals, airports, ports, office or public buildings".

- "Professionals" means "qualified personnel in accordance with EU or national legislation, where it exists. The equipment is installed by specialised personnel employed by the manufacturer, the user, a manufacturer representative or other specialised professionals responsible for the installation activity."

### ❖ Large scale stationary industrial tools (LSSIT)

Article 3(3) defines "large scale stationary tools – LSSIT" as follows:

> ***Article 3(3)***
> *"large-scale stationary industrial tools" means a*
> - *large-scale assembly of machines, equipment, and/or components,*
> - *functioning together for a specific application,*
> - *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.*

Only equipment which fulfils all the following conditions is excluded:

- A large scale 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 research and development facility.

"Large scale" in the context of the scope exclusion of "large scale stationary industrial tools" means "an assembly of machines or systems designed to be used in an industrial manufacturing facility, consisting of components and devices, where the combination can be intended to be placed on the market as a single tool for industrial applications.

"Tools" can be defined as "machines or systems designed to be used in industrial operations. They are installed by specialised personnel employed by the manufacturer, the user, a manufacturer representative or other specialised professionals responsible for the installation activity. They are permanently located during their phase of use."

The criteria to be defined for a better understanding and to decide whether a tool is large-scale stationary industrial tool are the following:

1. **Large-scale***:* a tool is to be considered "large-scale" because its physical volume, structure, lifespan, number of produced units or tailor-made characteristics, installation, handling, maintenance requirements, or a combination of any of these factors, make it different from commonly understood tools.

2. **Assembly of machines, equipment, and/or components, functioning together for a specific application:** The tool should consist in machines, equipment, and/or components that need to be installed together to perform a specific task. Equipment supplied as a single functional unit is not a large-scale stationary industrial tool. Equipment such as computers, installed at the same location but which can function separately are not considered as part of the large-scale stationary industrial tool.

3. **Permanently installed at a given place / stationary:** the tool should not, in principle, be moved/removed during its lifespan from the facility or the structure where it has been integrated / installed.

   The tool may still require mobility or continuous or semi-continuous movement to function. For example, a tool mounted on rails can still be considered large-scale stationary industrial tool.

4. **Installed, de-installed, used and maintained by professionals***:* the tool is installed, de-installed, used and maintained by specialised personnel.
   "Professionals" means "qualified personnel in accordance with EU or national legislation where it exists.

   Specialised personnel may be employed by the manufacturer, the user, a manufacturer representative or other specialised professionals responsible for the installation.

5. **Industrial manufacturing facility or research and development facility:** a large-scale stationary industrial tool is not intended for use in private residences.

   **Industrial manufacturing facility** extends to tools operating in areas such as mining, farming and handling facilities which are still encompassed in the "manufacturing" activities.

   **Research and development facility** refers to laboratories and research centres, public or private, where performed activities aim at discovering new knowledge about products, processes, and services.

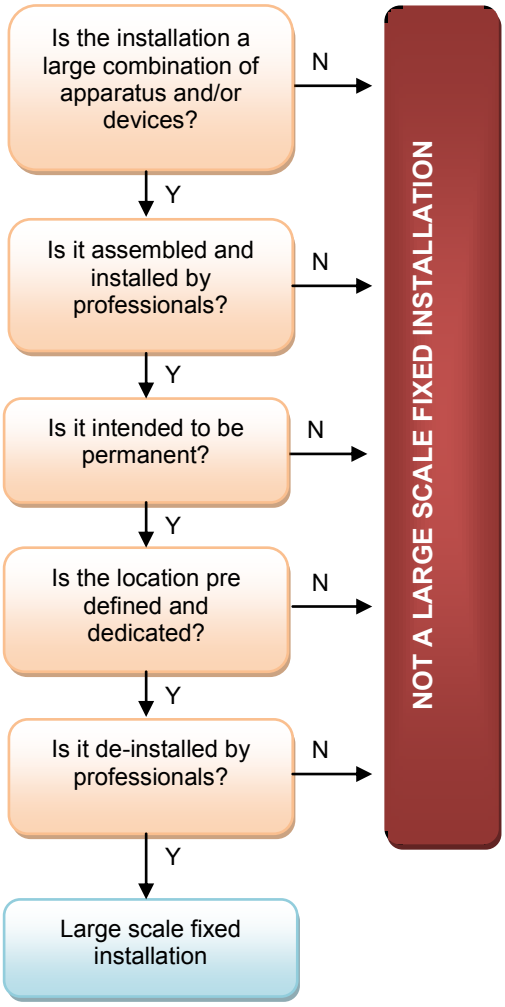
Article 2(4)(c) implies that equipment which is specifically designed, and is to be installed, as part of large-scale stationary industrial tool is excluded from this Directive, if it can fulfil its function only if it is part of that large-scale stationary industrial tool, and if it can be replaced only by the same specifically designed equipment.

Examples of large-scale stationary industrial tools include:

- Milling machines;
- Welding machines;
- Vehicle component assembling station;
- Machine tools;
- Paper production machines;
- Printing presses;
- Packaging machines;
- Textile machines;
- Industrial robots;
- Industrial measurement and monitoring platforms (e.g. for pulp and paper).

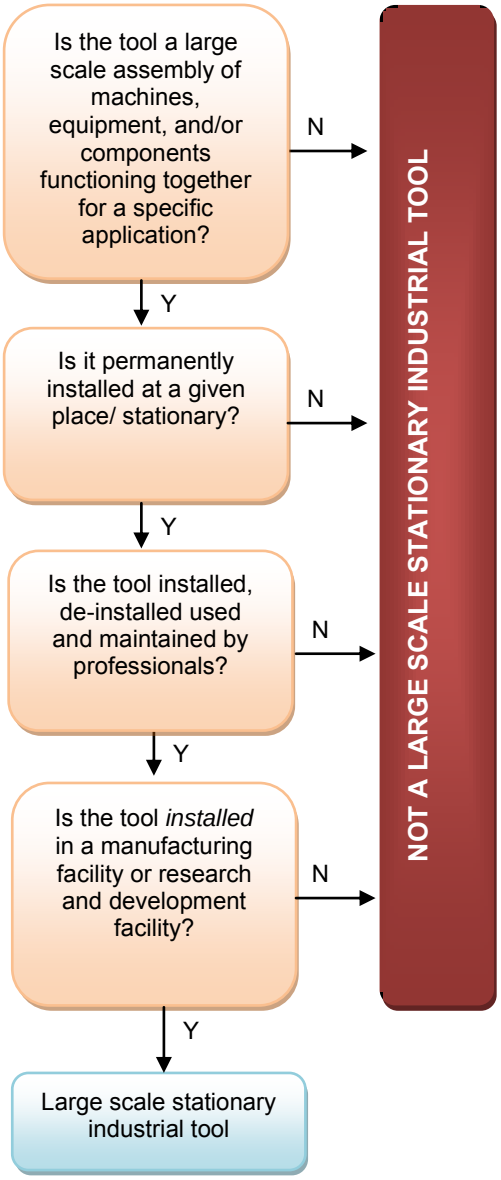
### ❖ RoHS Decision tree for LSFI

Manufacturer of fixed installations (or apparatus specifically designed to be installed in fixed installations) can use the following decision tree to decide if the particular installation meets the definition of a “large scale fixed installation”.



### ❖ RoHS Decision tree for LSSIT

The following decision tree helps determining whether a particular tool meets the definition of a "large-scale stationary industrial tool":



## 1.3.6. Components and parts

Single components or parts of finished products are not in the scope of the recast RoHS Directive by themselves. However, the Directive's approach of addressing material contents and restrictions of material use in a given finished product indirectly implies that its parts (material, components, sub-assemblies) need to meet the substance restriction requirements, unless an exemption applies that is listed in Annexes III and IV of the Directive or in finally adopted and published amendments to it. CE marking for components and parts is not required.

Article 4 of the RoHS recast sets specific provisions for **cables and spare parts** of EEE placed on the market:

> ***Article 4: Prevention***
> *1. Member States shall ensure that EEE placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, does not contain the substances listed in Annex II.*

Cables and spare parts are defined by Article 3(5) & 3(27):

> ***Article 3(5)***
> *"cables" means all cables with a rated voltage of less than 250 volts that serve as a connection or an extension to connect EEE to the electrical outlet or to connect two or more EEE to each other.*
>
> ***Article 3(27)***
> *"spare part" means a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part.*

"The Commission interprets Article 2(2) as meaning that electrical and electronic equipment which was outside the scope of Directive 2002/95/EC, but which would be covered by the new Directive, does not need to comply with the requirements of this Directive during a transitional period of eight years.

EEE which was outside the scope of Directive 2002/95/EC, but which would be covered by the new Directive, includes among others EEE, "cables" mentioned in Article 4 and the related definition in Article 3(5);"[19]

Therefore:

- Cables (as defined in Article 3(5)) fall under Category 11, and the substance restrictions and the DoC/CE marking requirements therefore apply from 22 July 2019;
- Wiring that is contained within or integral to, EEE does not meet the definition of "cable" given in Article 3(5). Instead, such wiring is part of the EEE and must therefore meet the material restrictions and timescale that apply to the EEE itself.

Specific provisions have been added in the recast RoHS Directive also concerning spare parts and repaired EEE (see Chapter 1.7 of this Guide).

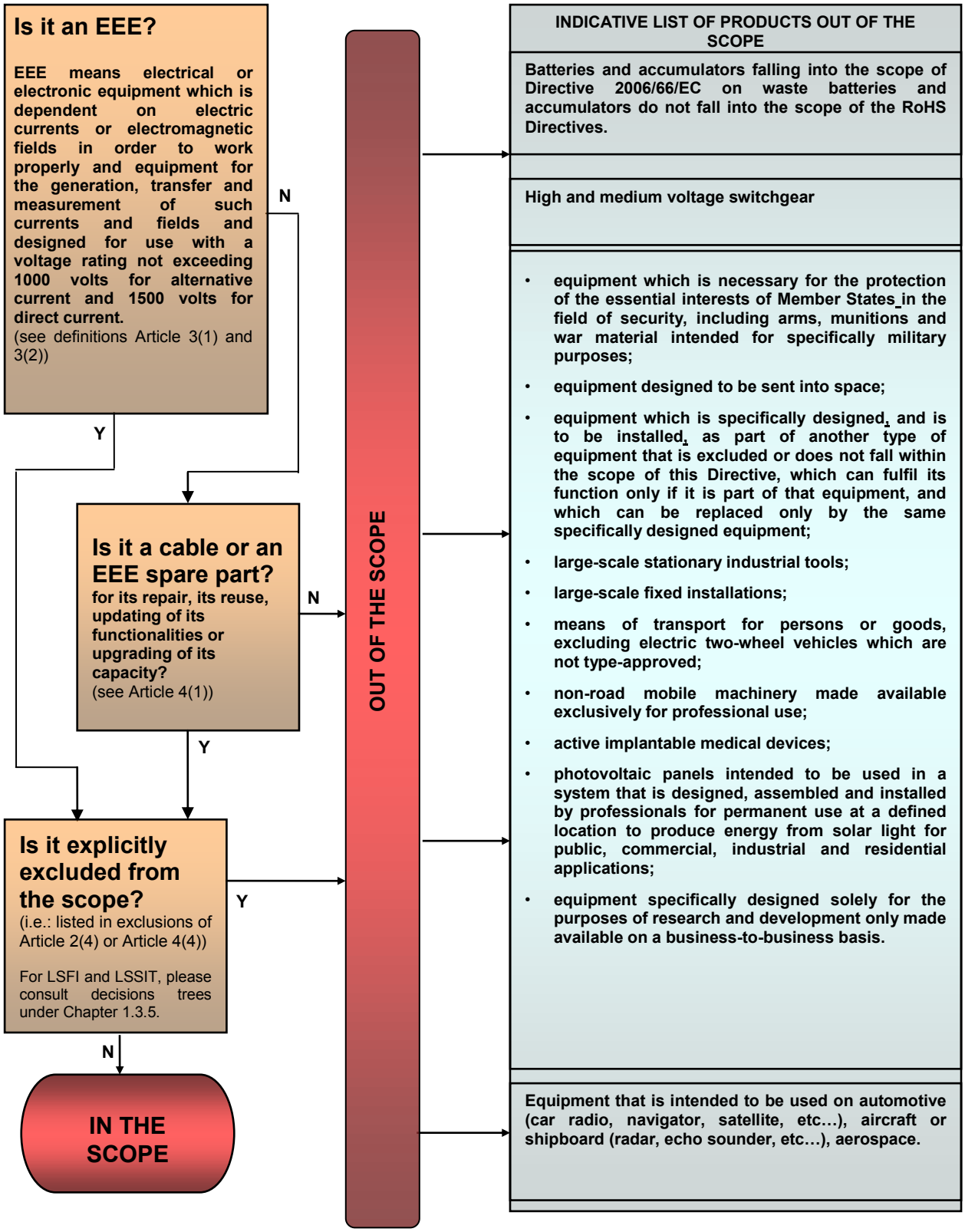
**Consumables and Accessories**: Consumables, such as CDs, DVDs, ink cartridges, floppy disks, badges, etc… do not fall in the scope of the RoHS recast as they are not electric or electronic equipment. Even if they have some electric or electronic components, they are not to be considered EEE according to the definition of Article 3(1).

For the purpose of the recast RoHS Directive, it is not required to affix the CE marking on components, parts, spare parts, consumables or accessories or to issue a Declaration of conformity.[20]

[19] Commission Statement 8117/11 ADD1 REV1
[20] Note: Such products may however bear the CE marking due to falling within the scope of other EU Directives or Regulations.

## 1.3.7. RoHS decision tree

The following RoHS decision tree summarises all the criteria analysed in this Guide and relevant to determine whether or not equipment falls within the scope of the recast RoHS Directive:




*) Cables (as defined in Article 3(5)) fall under Category 11, and the substance restrictions and the DoC/CE marking requirements therefore apply from 22 July 2019. Wiring that is contained within or integral to, EEE does not meet the definition of "cable" given in Article 3(5). Instead, such wiring is part of the EEE and must therefore meet the material restrictions and timescale that apply to the EEE itself.

## 1.3.8. Important dates

| **Dates after which EEE that is placed on the market must not contain the hazardous substances listed Annex II:** | |
|---|---|
| **Annex I of recast RoHS Directive** | **Starting dates**[21] |
| 1. Large household appliances | 1 July 2006 |
| 2. Small household appliances | 1 July 2006 |
| 3. IT and telecommunications equipment | 1 July 2006 |
| 4. Consumer equipment | 1 July 2006 |
| 5. Lighting equipment | 1 July 2006 |
| 6. Electrical and electronic tools (with the exception of large-scale stationary industrial tools) | 1 July 2006 |
| 7. Toys, leisure and sports equipment | 1 July 2006 |
| 8. Medical devices | 22 July 2014 |
| 8. In vitro medical devices | 22 July 2016 |
| 9. Monitoring and control instruments | 22 July 2014 |
| 9. Industrial monitoring and control instruments | 22 July 2017 |
| 10. Automatic dispensers | 1 July 2006 |
| 11. Other electrical and electronic equipment EEE not covered by any of the categories above | 22 July 2019 |

[21] Some argue that a new product in scope could fall under another category than Category 11. In that case, the deadline given in Article 2(2) applies also for such equipment new in scope. In addition, the ongoing discussion on a possible revision of Article 2(2) of RoHS II needs to be taken into account.

| **Dates after which cables or spare parts that are placed on the market must not contain hazardous substances:**[22] | |
|---|---|
| **Cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of :** | **Starting dates** |
| 1. EEE placed on the market after | 1 July 2006 |
| 2. Medical devices placed on the market after | 22 July 2014 |
| 3. In vitro diagnostic medical devices placed on the market after | 22 July 2016 |
| 4. Monitoring and control instruments placed on the market after | 22 July 2014 |
| 5. Industrial monitoring and control instruments placed on the market after | 22 July 2017 |
| 6. EEE which benefited from an exemption and the cables or spare parts for which were placed on the market after that exemption expired as far as that specific exemption is concerned. | Depending on validity date of relevant exemption |

## 1.4. TERMS AND DEFINITIONS (Article 3)

Legal certainty is a prerequisite for the proper implementation of the recast RoHS Directive. Common definitions are necessary to ensure that the technical requirements for RoHS compliance of all electrical and electronic equipment are exactly the same in all Member States in order to ensure a level playing field for manufacturers, free circulation and smooth market access for electrical and electronic equipment in the EU.

Article 3 of the recast RoHS Directive contains the following definitions:

| | | |
|---|---|---|
| **SCOPE**<br>**RELATED DEFINITIONS** | "Non- road mobile machinery made available exclusively for professional use" | *"non-road mobile machinery made available exclusively for professional use" means machinery, with an on-board power source, the operation of which requires either mobility or continuous or semi-continuous movement between a succession of fixed working locations while working, and is made available exclusively for professional use.* |
| | "Large scale stationary industrial tools" | *"large-scale stationary industrial tools" means a large-scale assembly of machines, equipment, and/or components, functioning together for a specific application, permanently installed and de-installed by* |

[22] Currently, there is no exclusion for spare parts for Category 11 in the recast RoHS Directive.

| | | |
|---|---|---|
| | | *professionals at a given place, and used and maintained by professionals in an industrial manufacturing facility or research and development facility.* |
| | "Large scale fixed installations" | *"large scale fixed installation" means a large scale combination of several types of apparatus and, where applicable, other devices, which are assembled, installed by professionals and intended to be used permanently in a pre-defined and dedicated location, and to be de-installed by professionals.* |
| | "Cables" | *"cables" means all cables with a rated voltage of less than 250V that serve as a connection or an extension to connect EEE to the electrical outlet or to connect two or more EEE to each other.* |
| | "Spare part" | *"spare part" means a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part.* |
| **DEFINITIONS RELATED TO RoHS COMPLIANCE** | "Homogeneous material" | *"homogeneous material" means one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes.* |
| **DEFINITIONS RELATED TO EXEMPTIONS** | "Availability of a substitute" | *"availability of a substitute" means the ability of a substitute to be manufactured and delivered within a reasonable period of time as compared with the time required for manufacturing and delivering the substances listed in Annex II.* |
| | "Reliability of a substitute" | *"reliability of a substitute" means the probability that an EEE using a substitute will perform a required function without failure under stated conditions for a stated period of time.* |
| **DEFINITIONS RELATED TO NEW LEGISLATIVE FRAMEWORK** | "Economic operator" | *"economic operators" means the manufacturer, the authorized representative, the importer and the distributor.* |
| | "Making available on the market" | *"making available on the market" means any supply of an EEE for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.* |
| | "Placing on the market" | *"placing on the market" means making available an EEE on the Union market for the first time.* |
| | "Harmonised standard" | *"harmonised standard" means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of* |

| | | |
|---|---|---|
| | | *rules on Information Society services(20) on the basis of a request made by the Commission in accordance with Article 6 of Directive 98/34/EC.* |
| | "Technical specification" | *"technical specification" means a document that prescribes technical requirements to be fulfilled by a product, process or service.* |
| | "Recall" | *"recall" means any measure aimed at achieving the return of a product that has already been made available to the end user.* |
| | "Withdrawal" | *"withdrawal" means any measure aimed at preventing a product in the supply chain from being made available on the market.* |

## 1.5. RESTRICTED SUBSTANCES (ARTICLE 4, ANNEX II, ARTICLES 6 AND 19-22)

### 1.5.1. Prevention (Article 4, Annex II)

The recast RoHS Directive restricts the placing on the market within the European Union of electrical and electronic equipment (EEE) "*including cables and spare parts for its repair, its reuse, updating of its functionalities and upgrading of its capacities*", which contain the substances listed in Annex II.

In comparison to Directive 2002/95/EC, the recast develops a legal text, which contains a more detailed and articulated information:

First, it avoids listing the restricted substances in the legal text of the Directive, by referring to a particular Annex II, which shall be reviewed by the Commission, under certain conditions and in application of a new substance evaluation method (see Chapter 1.5.2 and Chapter 3 of this Guide).

Secondly, the text makes explicit reference to cables and spare parts for the repair and the reuse of an EEE.

The recast does not add new substances to the list of restricted substances now spelled out in Annex II, so that, for the time being, it contains the same 6 substances as Directive 2002/95/EC; there are tolerated maximum concentration values for these substances by weight in homogeneous materials as specified in Annex II.

The substances and the related Maximum Concentration Values (MCVs) are the following:

| Substance | MCVs |
|---|---|
| Lead | 0,1 % |
| Mercury | 0,1 % |
| Cadmium | 0,01 % |
| Hexavalent chromium | 0,1 % |
| Polybrominated biphenyls (PBB) | 0,1 % |
| Polybrominated diphenyl ethers (PBDE) | 0,1 % |

The actual concentration value in % is obtained by dividing the weight of the substance by the weight of the homogeneous material that contains this substance multiplied by 100. Please note that the new Directive provides with the following definition of "homogeneous material" in Article 3(20):

***Article 3(20)***
"homogeneous material" means one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes.

With regard to maximum concentration value tolerances, the Commission, by means of the new instrument of delegated acts, is expected to define the details of compliance, with particular reference to surface coatings.

The recast RoHS Directive applies the material restrictions at different dates depending on the type of EEE, and also introduces a number of exemptions from the given restrictions (see Chapter 1.3 on scope and Chapter 1.6 on exemptions).

***Article 4: Prevention***
*1. Member States shall ensure that EEE placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, does not contain the substances listed in Annex II.*
*2. For the purposes of this Directive, no more than the maximum concentration value by weight in homogeneous materials as specified in Annex II shall be tolerated. The Commission shall adopt, by means of delegated acts in accordance with Article 20 and subject to the conditions laid down in Articles 21 and 22, detailed rules for complying with these maximum concentration values taking into account, inter alia, surface coatings.*
*3. Paragraph 1 shall apply to medical devices and monitoring and control instruments which are placed on the market from 22 July 2014, to in vitro diagnostic medical devices which are placed on the market from 22 July 2016 and to industrial monitoring and control instruments which are placed on the market from 22 July 2017.*
*4. Paragraph 1 shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of the following:*
*(a) EEE placed on the market before 1 July 2006;*
*(b) medical devices placed on the market before 22 July 2014;*
*(c) in vitro diagnostic medical devices placed on the market before 22 July 2016;*
*(d) monitoring and control instruments placed on the market before 22 July 2014;*
*(e) industrial monitoring and control instruments placed on the market before 22 July 2017;*
*(f) EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned.*
*5. Paragraph 1 shall not apply to reused spare parts, recovered from EEE placed on the market before 1 July 2006 and used in equipment placed on the market before 1 July 2016, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer.*
*6. Paragraph 1 shall not apply to the applications listed in Annexes III and IV.*

## 1.5.2. Review and amendment of list of restricted substances (Article 6)

An important modification to Directive 2002/95/EC is that the recast lists the restricted substances in a dedicated Annex, and not within the legal text of the Directive; although such a shift can seem only a formality, it allows the Commission (through the Comitology procedure) to add to the list of substances without modifying the legal body of the two pieces of legislation.

The first review of Annex II is expected to be carried out by the Commission by 22 July 2014.

With a reference to the review of the list of restricted substances, EU regulators introduced a new methodology for evaluating substances prior to reviewing existing or setting new restrictions:

First of all, the new methodology makes an explicit reference to Regulation (EC) No 1907/2006 on registration, evaluation and authorisation of chemicals (REACH Regulation), meaning that the Commission, when reviewing Annex II, takes into account, with particular regard, Annex XIV on authorisation and Annex XVII on restrictions of the REACH Regulation, by evaluating the coherence between the two pieces of legislation.

Moreover, in order to review and amend Annex II, the Commission is expected to take into account more implications, partly related to substances' effect on waste management operation or on the environment, partly related to exposure of workers, and finally the Commission shall evaluate the availability of substitutes or alternative technologies. An important modification is the obligation for the Commission to consult affected and interested parties, before amending Annex II, such as economic operators; furthermore, among the

information to be at the very least released by the Commission within the proposal of amending Annex II, it explicitly refers to socio-economic assessment.

With a view to substances to be added to Annex II in the future, there is a reference within the legal text of the new Directive to "*substances of very small size or internal or surface structure*" (nanomaterials); moreover, recital 10 states that "*the risks to human health and the environment arising from the use of Hexabromocyclododecane (HBCDD), Bis (2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP) and Dibutylphthalate (DBP) should be considered as a priority*".

***Article 6: Review and amendment of list of restricted substances in Annex II***
*1. With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and amendment of the list of restricted substances in Annex II shall be considered by the Commission before 22 July 2014, and periodically thereafter on its own initiative or following the submission of a proposal by a Member State containing the information referred to in paragraph 2.*

*The review and amendment of the list of restricted substances in Annex II shall be coherent with other legislation related to chemicals, in particular Regulation (EC) No 1907/2006, and shall take into account, inter alia, Annexes XIV and XVII to that Regulation. The review shall use publicly available knowledge obtained from the application of such legislation.*

*In order to review and amend Annex II, the Commission shall take special account of whether a substance, including substances of very small size or with a very small internal or surface structure, or a group of similar substances:*

*(a) could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE;*

*(b) could give rise, given its uses, to uncontrolled or diffuse release to the environment of the substance or could give rise to hazardous residues or transformation or degradation products through the preparing for re-use, recycling or other treatment of materials from waste EEE under current operational conditions;*

*(c) could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes;*

*(d) could be replaced by substitutes or alternative technologies which have less negative impacts. During that review, the Commission shall consult interested parties including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations.*

*2. The proposals to review and amend the list of restricted substances, or a group of similar substances, in Annex II shall contain at least the following information:*
*(a) precise and clear wording of the proposal;*
*(b) referenced and scientific evidence for the restriction;*
*(c) information on the use of the substance or the group of similar substances in EEE;*
*(d) information on detrimental effects and exposure in particular during waste EEE management operations;*
*(e) information on possible substitutes and other alternatives, their availability and reliability;*
*(f) justification for considering a Union-wide restriction as the most appropriate measure;*
*(g) socio-economic assessment.*

*3. The measures referred to in this Article shall be adopted by the Commission by means of delegated acts in accordance with Article 20 and subject to the conditions laid down in Articles 21 and 22.*

## 1.5.3. Procedure for reviewing Annex II (Articles 19-22)

With respect to the procedure for reviewing Annex II (Article 6) and to the rules for complying with maximum concentration values (Article 4(1)), the recast RoHS Directive gives the Commission the possibility to adopt delegated acts, in accordance to Article 290 of the Lisbon Treaty; this new procedure applies instead of the Co-decision procedure foreseen in Directive 2002/95/EC for establishing substance restrictions.

The Commission has received a delegation of power by the European Parliament and the Council to amend Annex II and to adopt rules to complying with maximum concentration values, for a period of 5 years following the entry into force of the new Directive. Such delegation of powers may be extended. Furthermore, the Commission must make a report on the use made of this delegated power at least 6 months before the expiry of the 5 year period.

In comparison with the Comitology procedure of the consolidated Directive, this new procedure introduces the possibility for both the Parliament and the Council to revoke at any time the delegation of powers, or to object to the delegated act, once it has been notified by the Commission.

For further details on Comitology, please consult Chapter 3 of this Guide.

## 1.6. EXEMPTIONS (ARTICLE 5, ANNEXES III-V)

The recast RoHS Directive exempts certain applications from the RoHS substance restrictions, because:

- The elimination or substitution via design changes or materials and components is technically or scientifically impracticable;
- The reliability of substitute is not ensured;
- The total negative environmental, health and consumer safety impact caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

The recast RoHS Directive defines availability and reliability in Article 3(25) as follows:

***Article 3(25)***
*"availability of a substitute" means the ability of a substitute to be manufactured and delivered within a reasonable period of time as compared with the time required for manufacturing and delivering the substances listed in Annex II.*
***Article 3(26)***
*"reliability of a substitute" means the probability that an EEE using a substitute will perform a required function without failure under stated conditions for a stated period of time.*

In general, each exemption included in the RoHS Annexes III and IV will be evaluated on a case by case basis taking into account:

- Non-technical practicability;
- Reliability of the substitute;
- Availability of substitutes;
- Socio-economic impact of substitution;
- Any potential impact on innovation.

Furthermore, before amending Annexes III and IV, the Commission shall consult stakeholders according to Article 5(7), and make the comments received publicly available.

Each exemption will have a validity period depending on the category of EEE. It will be decided on a case by case basis and can be renewed:

| **Annex where exemptions are listed on 21.07.2011** | **Categories concerned as defined in Annex I** | **Maximum validity period** |
|---|---|---|
| Annex III | 1-7 and 10 | Up to 5 years from the date the Directive enters into force |
| Annex III | 8, 9 | Up to 7 years from the dates laid down in Article 4(3) |
| Annex IV | 8, 9 | Up to 7 years from the dates laid down in Article 4(3) |

Any exemptions that are adopted after the publication of 2011/65/EU shall, for Categories 1 to 7, 10 and 11 have a validity period of up to 5 years and, for Categories 8 and 9, a validity period of up to 7 years (ref. Article 5(2)). The validity periods are to be decided on a case-by-case basis and may be renewed.

### 1.6.1. Application for an exemption

Annex V of the recast RoHS Directive introduces a list of information to be submitted with an exemption request in order to grant, renew or delete an exemption. The final format for the information documentation shall be decided by the European Commission.

Any such application can be submitted by a manufacturer, authorised representative of a manufacturer or any economic operator in the supply chain.

In particular, an application has to take into consideration an analysis of possible alternative substances and information related to the treatment of WEEE (points d) and e)) shall be highlighted.

The recast RoHS Directive sets clear obligations for all stakeholders related to actions and timing for the application of an exemption or for requesting a renewal. The procedure to adapt changes to Annex III and IV will be prepared by the Commission by means of individual delegated acts (following Article 20 – 22).

| Who? | When? | Action |
|---|---|---|
| The applicant (manufacturer, authorized representative of a manufacturer or economic operator in the supply chain) | Not later than 18 months before the exemption expires. | Submit to the Commission the application for a new exemption or renewal of an existing exemption in Annex III or IV. |
| The Commission | Within 15 days of receiving an application for a new exemption or a renewal of an existing exemption. | Acknowledge the receipt of an application in writing. |
| The Commission | Without delay after receiving an application for renewal. | Inform the Member States and make available the application an all supplementary information provided by the applicant.<br><br>Make a publically available summary of the application.<br><br>Evaluate the application and its justification. |
| The Commission | At the moment of publication of the Delegated Acts in the EU Official Journal | Take the decision on granting a new exemption. |
| The Commission | Not later than 6 months before the exemption expires | Take the decision on the renewal or deletion of an existing exemption. |

If the Commission is not able to take the decision within the given timeframe, the exemption remains valid until the final opinion is formulated.

If the exemption for renewal is rejected by the Commission or the exemption is deleted, there will be a transition period of 12-18 months maximum from the date when the decision was taken.

The recast RoHS Directive contains in its annexes III and IV the full list of all applicable exemptions (see page 47 of this Guide).

The following additional exemptions have been recently granted under RoHS1 via Commission Decision 2011/534/EU, published in the Official Journal of the EU on 8 September 2011:

- "7(c)-IV: Lead in PZT based dielectric ceramic materials for capacitors being part of integrated circuits or discrete semiconductors";

- "40: Cadmium in photoresistors for analogue optocouplers applied in professional audio equipment Expires on 31 December 2013".

Any further future exemption request under RoHS I would, if it is assessed as justified, also have to be granted in the form of a Commission Decision from the procedure perspective. These new Commission Decisions, as well as Decision 2011/534/EU, would remain valid until the repeal of Directive 2002/95/EC taking effect from 3 January 2013. A prolongation of such exemptions would by then require an inscription in the new Annexes III and/or Annex IV of the recast RoHS Directive.

The initial RoHS Directive 2002/95/EC and all its successive amendments amending the existing RoHS I exemptions annex[23] will be repealed with effect from 3 January 2013.

## 1.7. SPARE PARTS AND REPAIRED EEE

### 1.7.1. Spare parts

Article 3(27) of the recast RoHS Directive defines a "spare part" as:

> ***Article 3(27)***
> *"Spare part" means a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part.*

Unless excluded (see below), spare parts must meet the material restrictions specified in Annex II of the recast RoHS Directive, but do not require a CE marking or Declaration of Conformity ("DoC").

Articles 4(4) and 4(5) of the recast RoHS Directive permit the following exclusions:

- Spare parts, for the repair, the reuse, the updating of functionalities or upgrading of capacity of the following:
    - EEE placed on the market before 1 July 2006;
    - Medical devices placed on the market before 22 July 2014;
    - In vitro diagnostic medical devices placed on the market before 22 July 2016;
    - Monitoring and control instruments placed on the market before 22 July 2014;
    - Industrial monitoring and control instruments placed on the market before 22 July 2017;
    - EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned (see Annex III and Annex IV of the RoHS Directive for details of exemptions and dates).

The key date for the above exclusions is therefore the date at which the initial EEE was "placed on the market" - not the date when it was repaired, nor the date when the spare part was "placed on the market".

- Reused spare parts, recovered from EEE placed on the market before 1 July 2006 and used in equipment placed on the market before 1 July 2016, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer.

[23] Commission Decisions 2005/717/EC, 2005/747/EC, 2006/310/EC, 2006/690/EC, 2006/291/EC, 2006/692/EC, 2008/35/EC, 2008/385/EC, 2009/428/EC, 2009/443/EC, 2010/122/EU and 2010/571/EU.

Spare parts for equipment which is itself excluded by Article 2(4) of the recast RoHS Directive are also excluded.

Spare parts may also benefit from the exemptions listed in Annex III and Annex IV of the recast RoHS Directive.

### 1.7.2. Repaired EEE

EEE that is repaired does not need a new CE marking or DoC.

Repaired EEE can only be placed on the market as a "new" EEE if it complies with all applicable RoHS requirements as of that date.

Furthermore, the new EEE must satisfy the requirements of all other applicable European Directives/Regulations that apply as of the date when the new EEE is placed on the market. The relevant conformity assessment procedures must be applied, a new DoC must be drawn up, and appropriate markings applied.

## 1.8. ALIGNMENT WITH THE NEW LEGISLATIVE FRAMEWORK (ARTICLE 7-17, ANNEX VI)

In contrast to the initial RoHS Directive 2002/95/EC, the recast RoHS Directive was aligned with the "New Legislative Framework" (NLF). It therefore introduces clarified requirements applying on the different economic operators, including requirements regarding CE marking, conformity assessment and other obligations on economic operators[24].

The NLF consists of Regulation (EC) 765/2008[25] and Decision 768/2008/EC[26].

Regulation (EC) 765/2008 mainly gives general provisions on CE marking and market surveillance. In particular, it obliges all Members States to perform market surveillance systematically regarding all product-related aspects of European harmonisation legislation. There was no similar obligation for RoHS at the European level previously.

Decision 768/2006/EC defines reference text modules to harmonise many different Directives in view of horizontal elements, such as definitions, marking, requirements, conformity assessment procedures, obligations of manufacturers and other economic operators, etc.

The main reference base for the interpretation of articles aligning RoHS with the NLF (mainly Articles 7-17 and annex VI) is the "Guide to the implementation of directives based on the New Approach and the Global Approach" known as the "Blue Guide". This publication already answers many questions on horizontal elements of the NLF in general. As far as questions concerning horizontal issues remain open, they have to be answered horizontally in a revised version of the Blue Guide[27]. This Chapter therefore will concentrate only on the RoHS specific aspects.

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[24] Annex VI.3 includes a reference to "installer" in the bracket expression, as this entry has been copied from the model wording of Decision 768/2008, where it is relevant for Directives that include specific obligations for installers. The RoHS2 Directive does not include such specific obligations.
However, if he is also the final distributor in the Business-to-Business supply chain, an "installer" bears verification obligations of Article 10 RoHS2.

[25] Regulation 765/2008/EC of the European Parliament and of the Council of 8 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.(0J L 218, 13.8.2008, p. 30.)

[26] Decision 768/2008/EC of the European Parliament and of the Council of 8 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC(OJ L 218, 13.8.2008, p.82.)

[27] The European Commission indicated its willingness towards Orgalime to conclude the revision of the Blue Guide in order to give comprehensive and horizontal guidance to economic operators and market surveillance authorities. For further information please see http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf.

## 1.8.1. Conformity Assessment and Technical Documentation

Article 7 references Module A of Annex II to Decision 768/2008/EC. The conformity assessment procedure to be applied as such is "internal production control":

The manufacturer has to fulfil the legislative requirements applying to the product and declares under his sole responsibility that the product concerned satisfies the requirements of the legislative instruments that apply to it. Within this procedure the EU Declaration of conformity must be issued and technical documentation drawn up.

Annex II of Decision 768/2008/EC lists for Module A the following elements, which have to be part of the technical documentation "wherever applicable":

- General description of the product;
- Conceptual design and manufacturing drawings and schemes, with necessary explanations;
- Harmonized standards applied and/or relevant technical specifications;
- Test reports.

These elements are mostly similar to the required documentation according to other New Approach Directives.

There are no detailed provisions in the recast RoHS Directive on the contents of these documents. For further details regarding this point please see Chapter 1.8.4.

It must be possible in general to check the product's conformity to the requirements by examining the technical documentation. Usually, this goal will be achieved by design and production documents containing specifications of parts and materials used.

The level of technical documentation should depend on the risk that the restricted substances may be contained in certain materials or components. Components where by nature the risk of containing restricted substances is negligible need not be considered in detail.
In most other cases of built-in components the specifications, declarations of the supplier or contractual agreements may be sufficient.

Chemical tests and test reports are only needed as a last resort in very extreme cases where a high risk of violation of the maximum values is identified.

When choosing the appropriate documentation, the reliability of the supply chain and the individual circumstances of material technology have to be taken into account. These decisions are within the responsibility of the manufacturer. EN 50581 will help manufacturers to define the appropriate content of the technical documentation with specific reference to the recast RoHS Directive. (See also clause 1.8.4 on the role of harmonized standards.)

## 1.8.2. EU Declaration of Conformity (DoC)

The EU Declaration of Conformity in accordance with RoHS must, be issued for products which fall under one of the categories listed in Annex I of the recast RoHS Directive and has to be held by the manufacturer at the disposal of authorities.

A formal EU Declaration of Conformity can only be issued when the product is covered by the relevant Directive. However, in practice it is usual, and in the supply chain sometimes necessary, to state in a written document that a product complies with limit values for certain substances as set out in RoHS (including the permitted exemptions in Annexes III and IV) while the product itself is not covered by RoHS directly.

There are no direct legal requirements for such a voluntary manufacturer's declaration, but it should not be identified as an "EU Declaration of Conformity". The content and handling of these manufacturers' declarations are subject to private contractual negotiations between economic operators. The required CE marking of the product with regard to other directives is not affected.

In most cases a single product is also covered by other directives than RoHS. According to current provisions in the EC Directives, the manufacturer has the choice to issue a single combined Declaration of Conformity or to separate it into different declarations for each relevant directive.
It is possible that with the alignment of other directives to the "New Legislative Framework" in the near future, only one single declaration covering all relevant directives will be allowed for one product. (This may however not come into force before 2014).
However, at this stage Articles 7(c) and 13 of RoHS2 depart from Article 5 of model Decision 768/2008/EC. In particular, the NLF requirement that “any product should only have one Declaration of Conformity covering all relevant Community Acts that apply” has not been incorporated in RoHS2.

It is therefore at the discretion of the manufacturer or his authorised representative to draw up one or several declarations of conformity for a product covered by several directives in addition to the WEEE and RoHS Directives. According to the Blue Guide Chapter 5.4, where several directives apply to a product, the manufacturer or the authorised representative can include all the declarations in a single document.

Moreover, the DoC does not need to accompany the EEE: Article 7 requires the manufacturer “only” to “draw up” the declaration of conformity. Directives, which require the DoC to accompany the product, state this requirement clearly in the legal text. RoHS2 does not include such a requirement.

Thus, the distributor is not requested to have the Declaration of Conformity, but should facilitate the task of market surveillance authorities in acquiring it from the manufacturer.

For equipment requiring a CE marking with the numerical suffix identifying the notified body, no additional CE marking is required. It is advisable to add a statement in the DoC explaining that the notified body has not been involved in assessing the manufacturer processes to ensure RoHS compliance and that RoHS compliance is ensured under the sole responsibility of the manufacturer.

Annex VI(4) of the recast RoHS-Directive requires that the DoC includes an *"identification of EEE allowing traceability".* This requirement is based on Decision 768/2008/EC and will be introduced in the same wording in most if not all EC Directives. There are no detailed requirements for this identification. The manufacturer just has to make sure that there is a clear and unambiguous reference from the EU Declaration of Conformity to a specific product. The manufacturer can choose between several existing possibilities: type, type family, individual series number, etc.

## 1.8.3. Corrective Measures – Recall

Article 7(8) requires the manufacturer to take corrective measures immediately if he considers or has reason to believe that products he placed on the market are not in conformity with the Directive. Among other measures the "withdrawal or recall, if appropriate" is mentioned. This has been introduced based on decision 768/2008/EC into the RoHS Directive for harmonisation reasons among the different Directives that require CE marking.

If the threshold values for restricted substances are exceeded, in most cases it will be sufficient to improve the production process and to rework products in stock. Recall is only relevant in extreme cases and appropriate mainly for serious safety risks. In practice, recall is to be performed only in very few and exceptional cases. When considering a recall, the risk of the restricted substance has to be compared with the unavoidable environmental impact caused by the disposal of the recalled products. In many cases a correction of the products will not be possible and they will have to be disposed of. Therefore, it is questionable in most cases if a recall can reduce the environmental risk.

## 1.8.4. Harmonised Standards – Presumption of Conformity

Article 16 of the recast RoHS Directive introduces the presumption of conformity for harmonised standards listed in the Official Journal of the EU. If a manufacturer uses such a standard for his conformity assessment, market surveillance authorities are obliged to assume the relevant legal requirements of the Directive are met unless proven otherwise.

According to the Commission standardisation mandate[28], EN 50581:2012 *"Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances"* has been developed.
EN 50581 is expected to be published in the Official Journal of the European Union by the end of 2012 and its use will provide presumption of conformity.

EN 50581 describes three kinds of documents that can be used to demonstrate conformity to RoHS requirements:

- Supplier declarations and/or signed contractual agreements;
- Material declarations;
- Analytical test results.

With regard to analytical test results, EN 50581 requires the use of:

- EN 62321 "Electrotechnical products – Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers.

*NOTE: EN 62321 will be replaced by a series of standards designated EN 62321-x*

In addition, the following EN/IEC documents also provide useful supporting guidance:

- EN 62474 "Material declaration for products of and for the electrotechnical industry";
- IEC/PAS 62596 "Electrotechnical products - Determination of restricted substances – Sampling procedure – Guidelines".

IEC TR 62476 "Guidance for evaluation of products with respect to substance-use restrictions in electrical and electronic products".

## 1.8.5. Markings and Indications

For the purpose of effective market surveillance the recast RoHS Directive requires for the following types of markings and indications on the EEE:

- CE marking;
- Type, batch or serial number or other element allowing its identification;
- Name and address of the manufacturer;
- Name and address of the importer.

General and legally binding rules on CE marking are given in Regulation (EC) 765/2008. The CE marking is to be affixed on the product by the manufacturer if it is an EEE covered by RoHS or any other harmonization legislation requiring it. If the CE marking is affixed to a product it symbolises, that all CE-directives applicable for this product are fulfilled. On the other hand the CE marking is not allowed, if the product is not covered by any directive requiring it, even not if certain technical requirements are fulfilled.

The need for affixing identification on the product by means of a type, batch or serial number or other element allowing its identification corresponds to a similar requirement for an "identification of EEE allowing traceability" in the declaration of conformity according Annex IV of RoHS (see before clause 1.8.2). It is up to the manufacturer to choose a suitable and appropriate kind of identification enabling him to perform a recall also with respect to other directives covering the product.

In addition, the manufacturer's name and address has to be indicated. This is not the (legal) person who has produced the product effectively, but the one who takes the responsibility for the conformity of the product and who has to sign the declaration of conformity.

[28] The European Commission sent in October 2011 a standardisation mandate M/499 to CEN, CENELEC and ETSI for the development of European standards in the field of the restriction of the use of certain hazardous substances in electrical and electronic equipment.

If the manufacturer is situated outside the EEA[29], the name and address of the importer has to be given in addition.

The indications for the product identification, the manufacturer and the importer have to be affixed primarily on the EEE itself, but "where that is not possible", the Directive allows "that the required information is provided" on the packaging or in a document accompanying the EEE". There is no clear statement in the Directive as to what "not possible" means. One criterion is the size of the product or the structure of its surface. But also other reasons such as size, design, or severe economic reasons may be sufficient justifications for putting the indications on the packaging or the accompanying documents instead of the product itself. This question is relevant for all directives aligned with the New Legislative Framework and has to be clarified horizontally (see introduction of Chapter 1.8). The forthcoming revision of the Blue Guide will give further guidance.

## 1.9. PENALTIES (ARTICLE23)

The recast also reinforced the provision on penalties to be established by Member States in Article 23:

***Article 23: Penalties***
*The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by the date specified in Article 25 at the latest and shall notify it without delay of any subsequent amendment affecting them.*

## 1.10. REVIEW (ARTICLE 24)

The recast RoHS Directive introduces two review clauses:

- A review of the scope related provisions by 22 July 2014;
- A review of the entire legislation by 22 July 2021.

The relevant Article 24 reads as follows:

***Article 24: Review***
*1. No later than 22 July 2014 the Commission shall examine the need to amend the scope of this Directive in respect of the EEE referred to in Article 2, and shall present a report thereon to the European Parliament and the Council accompanied by a legislative proposal, if appropriate, with respect to any additional exclusions related to that EEE.*
*2. No later than 22 July 2021 the Commission shall carry out a general review of this Directive, and shall present a report to the European Parliament and the Council accompanied, if appropriate, by a legislative proposal.*

[29] EEA: European Economic Area consist of EU with Liechtenstein, Norway and Island

## 1.11. TRANSPOSITION (ARTICLE25) AND ENTRY INTO FORCE (ARTICLE 27)

Member States shall transpose the recast RoHS Directive into national law by 2 January 2013.
In the meantime, existing national transpositions of Directive 2002/95/EC remain valid.

Article 25 states:

> ***Article 25: Transposition***
> *1. Member States shall adopt and publish, by 2 January 2013, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.*
>
> *When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.*
>
> *2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.*

Article 27 states:

> ***Article 27: Entry into force***
> *This Directive shall enter into force on the 20th day following that of its publication in the Official Journal of the European Union.*

The recast RoHS Directive has been published in the Official Journal of the EU on 1 July 2011.
Therefore, the recast RoHS Directive entered into force on 21 July 2011.

## 2. QUESTIONS CONCERNING ROHS COMPLIANCE

Whenever there is a new or an amended directive, customers/purchasers often ask for immediate confirmation from their suppliers that all items supplied to them will meet the new or changed requirements.

The recast RoHS Directive has a long transition period overall, with a number of scope issues to be clarified during that period, and, given the scope-related complexities and their differing timescales, the simple answer "Our products will continue to meet the requirements of all relevant directives, including those of RoHS if/where applicable" may not suffice.

The following alternative may satisfy general enquiries:

"Our products will continue to meet the requirements of all relevant directives, including those of RoHS if /where applicable. Any of our products affected by or coming into the RoHS scope for the first time, as a result of the inclusion in the recast Directive of product Categories 8, 9 or (the new) 11, changes to the exclusions or changes to exempted applications, will meet these new requirements from their due dates, or enable a finished product into which they may be incorporated to do so."

If the queries call for more specific information, or concern a particular item you supply, please refer to the appropriate sections of this guide for precise details of timescales, exclusions etc. If in any doubt or you experience difficulty in explaining these regulatory changes to your customers during this transitional period, contact your national Orgalime member for assistance.

N.B.: One of the most frequently asked questions concerns "fixed installations" (see Chapter 1.2 of this Guide).

## 3. COMITOLOGY: RELEVENT ASPECTS FOR THE IMPLEMENTATION OF THE RECATS ROHS DIRECTIVE (ARTICLES 19-22)

Under the initial RoHS Directive 2002/95/EC, the European Parliament and Council have already delegated certain implementation powers to the Commission under the so-called Comitology procedure (e.g.: amend the exemptions-annex to technical adaptation and scientific progress).

The recast RoHS Directive foresees the use of Comitology for the following issues:[30]

- Review and amendment of list of restricted substances in Annex II (Article 6);
- Details on compliance with Maximum Concentration Values for restricted substances (Article 4);
- Review and amendment of RoHS exemption Annexes (Article 5, Annexes III and IV);
- Adoption of a harmonised application format for exemptions and guidelines (Article 5 and Annex V).

In comparison to the initial RoHS Directive 2002/95/EC, however, there have been significant procedural changes brought to the so called Comitology procedure, which will now be relevant for the implementation of the recast RoHS Directive:

- The Treaty of the Functioning of the European Union ("Lisbon Treaty") introduces two different types of Comitology acts, delegated acts (Article 290) and implementing acts (Article 291);
- The former Comitology decision 1999/468/EC (specifying the so far relevant "regulatory committee procedure with scrutiny") has been repealed with the adoption of Regulation EU (No) 182/2011 and will not apply for the implementation of the recast RoHS Directive. Until repeal of Directive 2002/95/EC, however, the effects of Article 5(a) of Decision 1999/468/EC (regulatory committee procedure with scrutiny) are maintained;

[30] Contrary to the issues listed here, the review and amendment of the **scope** of the directive will not be subject to Comitology but to the ordinary legislative procedure (former co-decision procedure with involvement of the EP and Council).

- The Commission has provided additional information on the application of Article 290 on delegated acts in a specific a Communication issued in December 2009;
- Regulation EU (No) 182/2011 lays down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers under Article 291. This EU Regulation distinguishes between the advisory procedure and the examination procedure for the adoption of implementing acts. For the implementation of Article 291 under the recast RoHS Directive, the examination procedure will apply.

**Article 290 (delegated acts)** applies for:

- The review and amendment of the Annex II list of restricted substances (Article 6(1) and 6(3) recast RoHS Directive);
- Details on compliance with Maximum Concentration Values (Article 4(2) recast RoHS Directive), and
- Individual RoHS exemption requests (Article 5(1) recast RoHS Directive).

**Article 291 and subsequent Regulation 182/2011 (implementing acts via examination procedure)** applies for the establishment format for applications for exemptions and related guidelines (Article 5(8) recast RoHS Directive). In this work, the Commission shall be assisted by a Committee.

***Article 290 Lisbon Treaty***
*1. A legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act.*
*The objectives, content, scope and duration of the delegation of power shall be explicitly defined in the legislative acts. The essential elements of an area shall be reserved for the legislative act and accordingly shall not be the subject of a delegation of power.*
*2. Legislative acts shall explicitly lay down the conditions to which the delegation is subject; these conditions may be as follows:*
*(a) the European Parliament or the Council may decide to revoke the delegation;*
*(b) the delegated act may enter into force only if no objection has been expressed by the European Parliament or the Council within a period set by the legislative act.*
*For the purposes of (a) and (b), the European Parliament shall act by a majority of its component members, and the Council by a qualified majority.*
*3. The adjective "delegated" shall be inserted in the title of delegated acts.*

***Article 291 Lisbon Treaty***
*1. Member States shall adopt all measures of national law necessary to implement legally binding Union acts.*
*2. Where uniform conditions for implementing legally binding Union acts are needed, those acts shall confer implementing powers on the Commission, or, in duly justified specific cases and in the cases provided for in Articles 24 and 26 of the Treaty on European Union, on the Council.*
*3. For the purposes of paragraph 2, the European Parliament and the Council, acting by means of regulations in accordance with the ordinary legislative procedure, shall lay down in advance the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.*
*4. The word 'implementing' shall be inserted in the title of implementing acts.*

***Article 19: Committee procedure***
*1. The Commission shall be assisted by the committee set up pursuant to Article 39 of Directive 2008/98/EC. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.*
*2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.*

The recast RoHS Directive also includes the following **specific provisions regarding delegated acts**:

- Exercise of the delegation (Article 20);
- Possibilities of the European Parliament and Council to revoke the delegation at any time (Article 21);
- Possibility of the European Parliament and Council to object to a delegated act (Article 22);

***Article 20: Exercise of the delegation***
*1. The powers to adopt the delegated acts referred to in Article 4(2), Article 5(1) and Article 6 shall be conferred on the Commission for a period of 5 years from ...*.*
*The Commission shall draw up a report in respect of delegated powers at the latest 6 months before the end of the 5 year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21.*
*2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.*
*3. The powers to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 21 and 22.*

***Article 21: Revocation of the delegation***
*1. The delegation of power referred to in Article 4(2), Article 5(1) and Article 6 may be revoked at any time by the European Parliament or by the Council.*
*2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of powers shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible reasons for a revocation.*
*3. The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the Official Journal of the European Union.*

***Article 22: Objections to delegated acts***
*1. The European Parliament or the Council may object to a delegated act within a period of two months from the date of notification.*
*At the initiative of the European Parliament or the Council that period shall be extended by two months.*
*2. If, on expiry of the period referred to in paragraph 1, neither the European Parliament nor the Council has objected to the delegated act it shall be published in the Official Journal of the European Union and shall enter into force on the date stated therein.*
*The delegated act may be published in the Official Journal of the European Union and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.*
*3. If the European Parliament or the Council objects to the delegated act within the period referred to in paragraph 1, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.*

The recast RoHS Directive also foresees **stakeholder consultations in the context of Comitology:**

***Article 5(7):***
*Before Annexes are amended, the Commission shall inter alia consult economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations and make the comments received publicly available.*

***Article 6(1):***
*During that review, the Commission shall consult interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations.*

***Recital 25: Delegated acts***
*For the purposes of achieving the objectives of this Directive the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the TFEU in respect of amendments to Annex II, detailed rules for complying with maximum concentration values, and the adaptation to technical and scientific progress of Annexes III and IV. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level.*

| SUMMARY TABLE | |
|---|---|
| **Delegated acts (Article 290 Lisbon Treaty)** | **Implementing acts (Article 291 Lisbon Treaty)** |
| Relevant for:<br>• the review and amendment of the Annex II - list of restricted substances (Article 6(1) and 6(3) recast RoHS Directive)<br>• details on compliance with Maximum Concentration Values (Article 4(2) recast RoHS Directive) and<br>• individual RoHS exemption requests (Article 5(1) recast RoHS Directive). | Relevant for:<br>• the establishment of the format for applications for exemptions and related guidelines (Article 5(8) recast RoHS Directive). |
| The implementing powers are delegated for a period of 5 years and shall be automatically extended for further 5 years unless the EP or Council revoke the delegation. | |
| As soon as adopted, the act shall be notified to EP and Council simultaneously. | |
| • Member States experts (Technical Adaptation Committee) and EP do not have an advance voting right (prior to adoption of the act), but:<br>• Member States and the European Parliament have a right to object to an act adopted by the Commission within 4 months maximum after its notification to the EP/ Council and before its publication in the Official Journal.<br>• In case of objection, the act shall not enter into force. | • The European Parliament and Council have the right of scrutiny at any time of the procedure.<br>• Act shall be adopted in accordance with examination procedure (Article 5 of Regulation EU (No) 182/2011):<br>o In case of a positive opinion of the Committee, the Commission shall adopt the act.<br>o In case of a negative opinion of the Committee, the Commission shall not adopt (unless exceptional case allows adoption) - the Commission can submit proposal to the Appeal Committee within 1 month, or submit a new/amended version within 2 months to the Committee<br>o If the Committee has delivered no opinion:<br>a) The Commission may adopt or submit amended version to Committee<br>b) However, the Commission shall not adopt if act concerns protection of health or safety of humans, animals or plants, OR, if a simple majority of the Committee opposed adoption. In such cases, the Commission can submit proposal to the Appeal Committee within 1 month, or submit a new/amended version within 2 months to the Committee<br>• The examination procedure maintains the same voting system as the former regulatory procedure, i.e.: adoption requires a qualified majority in favour. |
| • EP and Council have the right to revoke the delegation at any time. | |

## ANNEX A: SNAPSHOT OF IMPORTANT DEADLINES TO REMEMBER

### 2011

**01.07. :**
**Publication** of Recast RoHS Directive in Official Journal of the EU

**21.07. :**
**Entry into force** of Recast RoHS Directive

### 2013

**02.01. :**
**Transposition** of Recast RoHS Directive into national law

**03.01. :**
**Repeal** of initial RoHS Directive 2002/95/EC and its successive amendments taking effect

### 2014

**22.07. :**
**Review** of scope and exclusion (art.24)

**Categories 8 & 9 of Annex I** not to contain:
•Lead
•Mercury
•Cadmium
•Hexavalent chromium
•PBB
•PBDE
(art.4.3)

**Review of Annex II** - list of restricted substances (art.6.1)

### 2016

**22.07. :**
**In vitro medical devices** not to contain the substances listed in Annex II.
(art.4.3)

### 2017

**22.07. :**
**Industrial monitoring and control instruments** not to contain the substances listed in Annex II:
•Lead
•Mercury
•Cadmium
•Hexavalent chromium
•PBB
•PBDE
(art.4.3)

### 2019

**22.07. :**
**Cat.11** to come into scope (therefore, scope to cover all EEE unless explicitly excluded; art.2, annex I)

### 2021

**22.07. :**
**General review** of Recast RoHS Directive (art.24)

**Continuous Implementation activities in Comitology**

# ANNEX B: CORRELATION TABLE (ANNEX VIII)

| Directive 2002/95/EC | This Directive (2011/65/EU) |
|---|---|
| Article 1 | Article 1 |
| Article 2(1) | Article 2(1), 2(2), Annex I |
| Article 2(2) | Article 2(3) |
| Article 2(3) | Article 2(4), introductory wording |
| - | Article 2(4) |
| Article 3(a) | Article 3(a),(b) |
| Article 3(b) | - |
| - | Article 3(f)-(ab) |
| Article 4(1) | Article 4(1), Annex II |
| - | Article 4(3)-(4) |
| Article 4(2) | Article 4(6) |
| Article 4(3) | - |
| Article 5(1), introductory wording | Article 5(1), introductory wording |
| Article 5(1)(a) | Article 4(2) |
| Article 5(1)(b) | Article 5(1)(a), first and third indents |
| - | Article 5(1)(a), second indent<br><br>Article 5(1)(a), final paragraph |
| Article 5(1)(c) | Article 5(1)(b) |
| - | Article 5(2)<br><br>Article 5(3)-(6) |
| Article 5(2) | Article 5(7) |
| - | Article 5(8) |
| Article 6 first, third, fourth indents | Article 6 |
| - | Article 7-18 |
| Article 7 | Articles 19-22 |
| Article 8 | Article 23 |
| Article 9 | Article 25 |
| - | Article 26 |
| Article 10 | Article 27 |
| Article 11 | Article 28 |
| - | Annex I- II |
| Annex, points 1-28 | Annex III, points 1-28 |
| Annex, point 29, first subparagraph | Annex III, point 29, first subparagraph |

| | |
|---|---|
| Annex, point 29, second subparagraph | Article 4(2) |
| Annex, points 30-32 | Annex III, points 30-32 |
| - | Annex IV, V, VI -VIII. |

# ANNEX C: CONSOLIDATED TEXT OF RECAST DIRECTIVE



**DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of 8 June 2011**

**on the restriction of the use of certain hazardous substances in electrical and electronic equipment**

**(recast)**

**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee ([1]),

Having regard to the opinion of the Committee of Regions ([2]),

Acting in accordance with the ordinary legislative procedure ([3]),

Whereas:

(1) A number of substantial changes are to be made to Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ([4]). In the interest of clarity, that Directive should be recast.

(2) The disparities between the laws or administrative measures adopted by the Member States regarding the restriction of the use of hazardous substances in electrical and electronic equipment (EEE) could create barriers to trade and distort competition in the Union and may thereby have a direct impact on the establishment and functioning of the internal market. It therefore appears necessary to lay down rules in this field and to contribute to the protection of human health and the environmentally sound recovery and disposal of waste EEE.

(3) Directive 2002/95/EC provides that the Commission shall review the provisions of that Directive, in particular, in order to include in its scope equipment which falls within certain categories and to study the need to adapt the list of restricted substances on the basis of scientific progress, taking into account the precautionary principle, as endorsed by Council Resolution of 4 December 2000.

(4) Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste ([5]) gives first priority to prevention in waste legislation. Prevention is defined, inter alia, as measures that reduce the content of harmful substances in materials and products.

(5) Council Resolution of 25 January 1988 on a Community action programme to combat environmental pollution by cadmium ([6]) invited the Commission to pursue without delay the development of specific measures for such a programme. Human health also has to be protected and an overall strategy that in particular restricts the use of cadmium and stimulates research into substitutes should therefore be implemented. The Resolution stresses that the use of cadmium should be limited to cases where suitable alternatives do not exist.

(6) Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants ([7]) recalls that the objective of protecting the environment and human health from persistent organic pollutants cannot be sufficiently achieved by the Member States, owing to the transboundary effects of those pollutants, and can therefore be better achieved at Union level. Pursuant to that Regulation, releases of persistent organic pollutants, such as dioxins and furans, which are unintentional by-products of industrial processes, should be identified and reduced as soon as possible with the ultimate aim of elimination, where feasible.

(7) The available evidence indicates that measures on the collection, treatment, recycling and disposal of waste EEE as set out in Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE) ([8]) are necessary to reduce the waste management problems associated with the heavy metals and flame retardants concerned. In spite of those measures, however, significant parts of waste EEE will continue to be found in the current disposal routes inside or outside the Union. Even if waste EEE were collected separately and submitted to recycling processes, its content of mercury, cadmium, lead, chromium VI, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) would be likely to pose risks to health or the environment, especially when treated in less than optimal conditions.

([1]) OJ C 306, 16.12.2009, p. 36.
([2]) OJ C 141, 29.5.2010, p. 55.
([3]) Position of the European Parliament of 24 November 2010 (not yet published in the Official Journal) and decision of the Council of 27 May 2011.
([4]) OJ L 37, 13.2.2003, p. 19.
([5]) OJ L 312, 22.11.2008, p. 3.
([6]) OJ C 30, 4.2.1988, p. 1.
([7]) OJ L 158, 30.4.2004, p. 7.
([8]) OJ L 37, 13.2.2003, p. 24.

(8) Taking into account technical and economic feasibility, including for small and medium sized enterprises (SMEs), the most effective way of ensuring a significant reduction of risks to health and the environment relating to those substances, in order to achieve the chosen level of protection in the Union, is the substitution of those substances in EEE by safe or safer materials. Restricting the use of those hazardous substances is likely to enhance the possibilities and economic profitability of recycling of waste EEE and decrease the negative impact on the health of workers in recycling plants.

(9) The substances covered by this Directive are scientifically well researched and evaluated and have been subject to different measures both at Union and at national level.

(10) The measures provided for in this Directive should take into account existing international guidelines and recommendations and should be based on an assessment of available scientific and technical information. The measures are necessary to achieve the chosen level of protection of human health and the environment, with due respect for the precautionary principle, and having regard to the risks which the absence of measures would be likely to create in the Union. The measures should be kept under review and, if necessary, adjusted to take account of available technical and scientific information. The annexes to this Directive should be reviewed periodically to take into account, inter alia, Annexes XIV and XVII to 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) and establishing a European Chemicals Agency ([1]). In particular, the risks to human health and the environment arising from the use of Hexabromocyclododecane (HBCDD), Bis (2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP) and Dibutyl phthalate (DBP) should be considered as a priority. With a view to further restrictions of substances, the Commission should re-investigate the substances that were subject to previous assessments, in accordance with the new criteria set out in this Directive as part of the first review.

(11) This Directive supplements the general Union waste management legislation, such as Directive 2008/98/EC and Regulation (EC) No 1907/2006.

(12) A number of definitions should be included in this Directive in order to specify its scope. In addition, the definition of 'electrical and electronic equipment' should be complemented by a definition of 'dependent', to cover the multipurpose character of certain products, where the intended functions of EEE are to be determined on the basis of objective characteristics, such as the design of the product and its marketing.

([1]) OJ L 396, 30.12.2006, p. 1.

(13) 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 ([2]) enables specific ecodesign requirements to be set for energy-related products which may also be covered by this Directive. Directive 2009/125/EC and the implementing measures adopted pursuant to it are without prejudice to Union waste management legislation.

(14) This Directive should apply without prejudice to Union legislation on safety and health requirements and specific Union waste management legislation, in particular 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 ([3]) and Regulation (EC) No 850/2004.

(15) The technical development of EEE without heavy metals, PBDE and PBB should be taken into account.

(16) As soon as scientific evidence is available, and taking into account the precautionary principle, the restriction of other hazardous substances, including any substances of very small size or with a very small internal or surface structure (nanomaterials) which may be hazardous due to properties relating to their size or structure, and their substitution by more environmentally friendly alternatives which ensure at least the same level of protection of consumers should be examined. To this end, the review and amendment of the list of restricted substances in Annex II should be coherent, maximise synergies with, and reflect the complementary nature of the work carried out under other Union legislation, and in particular under Regulation (EC) No 1907/2006 while ensuring the mutually independent operation of this Directive and that Regulation. Consultation with the relevant stakeholders should be carried out and specific account should be taken of the potential impact on SMEs.

(17) The development of renewable forms of energy is one of the Union's key objectives, and the contribution made by renewable energy sources to environmental and climate objectives is crucial. Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources ([4]) recalls that there should be coherence between those objectives and other Union environmental legislation. Consequently, this Directive should not prevent the development of renewable energy technologies that have no negative impact on health and the environment and that are sustainable and economically viable.

([2]) OJ L 285, 31.10.2009, p. 10.
([3]) OJ L 266, 26.9.2006, p. 1.
([4]) OJ L 140, 5.6.2009, p. 16.

(18) Exemptions from the substitution requirement should be permitted if substitution is not possible from the scientific and technical point of view, taking specific account of the situation of SMEs or if the negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the environmental, health and consumer safety benefits of the substitution or the reliability of substitutes is not ensured. The decision on exemptions and on the duration of possible exemptions should take into account the availability of substitutes and the socioeconomic impact of substitution. Life-cycle thinking on the overall impacts of exemptions should apply, where relevant. Substitution of the hazardous substances in EEE should also be carried out in such a way as to be compatible with the health and safety of users of EEE. The placing on the market of medical devices requires a conformity assessment procedure, according to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1] and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices [2], which could require the involvement of a notified body designated by competent authorities of Member States. If such a notified body certifies that the safety of the potential substitute for the intended use in medical devices or in vitro diagnostic medical devices is not demonstrated, the use of that potential substitute will be deemed to have clear negative socioeconomic, health and consumer safety impacts. It should be possible, from the date of entry into force of this Directive, to apply for exemptions for equipment, even before the actual inclusion of that equipment in the scope of this Directive.

(19) Exemptions from the restriction for certain specific materials or components should be limited in their scope and duration, in order to achieve a gradual phase-out of hazardous substances in EEE, given that the use of those substances in such applications should become avoidable.

(20) As product reuse, refurbishment and extension of lifetime are beneficial, spare parts need to be available.

(21) Procedures for assessing the conformity of EEE subject to this Directive should be consistent with relevant Union legislation, in particular Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products [3]. Harmonising conformity assessment procedures should give manufacturers legal certainty as to what they have to provide as proof of compliance to the authorities throughout the Union.

(22) The conformity marking applicable for products at Union level, CE marking, should also apply to EEE that is subject to this Directive.

(23) The market surveillance mechanisms laid down by Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products [4] provide the safeguard mechanisms to check compliance with this Directive.

(24) In order to ensure uniform conditions for the implementation of this Directive, particularly with regard to the guidelines and format of applications for exemptions, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers [5].

(25) For the purposes of achieving the objectives of this Directive the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union in respect of amendments to Annex II, detailed rules for complying with maximum concentration values, and the adaptation of Annexes III and IV to technical and scientific progress. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.

(26) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.

(27) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and application of the Directive set out in Annex VII, Part B.

(28) When reviewing this Directive, a thorough analysis of its coherence with Regulation (EC) No 1907/2006 should be carried out by the Commission.

(29) In accordance with paragraph 34 of the Interinstitutional Agreement on better law-making [6], Member States are encouraged to draw up, for themselves and in the interests of the Union, their own tables, which will, as far as possible, illustrate the correlation between this Directive and their transposition measures, and to make those tables public.

[1] OJ L 169, 12.7.1993, p. 1.
[2] OJ L 331, 7.12.1998, p. 1.
[3] OJ L 218, 13.8.2008, p. 82.
[4] OJ L 218, 13.8.2008, p. 30.
[5] OJ L 55, 28.2.2011, p. 13.
[6] OJ C 321, 31.12.2003, p. 1.

(30) Since the objective of this Directive, namely to establish restrictions on the use of hazardous substances in EEE, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the problem and its implications in respect of other Union legislation on recovery and disposal of waste and areas of common interest, such as human health protection, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

**Subject matter**

This Directive lays down rules on the restriction of the use of hazardous substances in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE.

*Article 2*

**Scope**

1. This Directive shall, subject to paragraph 2, apply to EEE falling within the categories set out in Annex I.

2. 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.

3. This Directive shall apply without prejudice to the requirements of Union legislation on safety and health, and on chemicals, in particular Regulation (EC) No 1907/2006, as well as the requirements of specific Union waste management legislation.

4. This Directive does not apply to:

(a) equipment which is necessary for the protection of the essential interests of the security of Member States, including arms, munitions and war material intended for specifically military purposes;

(b) equipment designed to be sent into space;

(c) equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment;

(d) large-scale stationary industrial tools;

(e) large-scale fixed installations;

(f) means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved;

(g) non-road mobile machinery made available exclusively for professional use;

(h) active implantable medical devices;

(i) photovoltaic panels intended to be used in a system that is designed, assembled and installed by professionals for permanent use at a defined location to produce energy from solar light for public, commercial, industrial and residential applications;

(j) equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis.

*Article 3*

**Definitions**

For the purposes of this Directive, the following definitions shall apply:

(1) 'electrical and electronic equipment' or 'EEE' means equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1 000 volts for alternating current and 1 500 volts for direct current;

(2) for the purposes of point 1, 'dependent ' means, with regard to EEE, needing electric currents or electromagnetic fields to fulfil at least one intended function;

(3) 'large-scale stationary industrial tools' means a large-scale assembly of machines, equipment, and/or components, functioning together for a specific application, 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;

(4) 'large-scale fixed installation' means a large-scale combination of several types of apparatus and, where applicable, other devices, which are assembled and installed by professionals, intended to be used permanently in a pre-defined and dedicated location, and de-installed by professionals;

(5) 'cables' means all cables with a rated voltage of less than 250 volts that serve as a connection or an extension to connect EEE to the electrical outlet or to connect two or more EEE to each other;

(6) 'manufacturer' means any natural or legal person who manufactures an EEE or who has an EEE designed or manufactured and markets it under his name or trademark;

(7) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

(8) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an EEE available on the market;

(9) 'importer' means any natural or legal person established within the Union, who places an EEE from a third country on the Union market;

(10) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;

(11) 'making available on the market' means any supply of an EEE for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(12) 'placing on the market' means making available an EEE on the Union market for the first time;

(13) 'harmonised standard' means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services [1] on the basis of a request made by the Commission in accordance with Article 6 of Directive 98/34/EC;

(14) 'technical specification' means a document that prescribes technical requirements to be fulfilled by a product, process or service;

(15) 'CE marking' means a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

(16) 'conformity assessment' means the process demonstrating whether the requirements of this Directive relating to an EEE, are met;

(17) 'market surveillance' means the activities carried out and measures taken by public authorities to ensure that EEE complies with the requirements set out in this Directive and does not endanger health, safety or other issues of public interest protection;

(18) 'recall' means any measure aimed at achieving the return of a product that has already been made available to the end user;

(19) 'withdrawal' means any measure aimed at preventing a product in the supply chain from being made available on the market;

(20) 'homogeneous material' means one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes;

(21) 'medical device' means a medical device within the meaning of point (a) of Article 1(2) of Directive 93/42/EEC and which is also EEE;

(22) 'in vitro diagnostic medical device' means an in vitro diagnostic medical device within the meaning of point (b) of Article 1(2) of Directive 98/79/EC;

(23) 'active implantable medical device' means any active implantable medical device within the meaning of point (c) of Article 1(2) of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices [2];

(24) 'industrial monitoring and control instruments' means monitoring and control instruments designed for exclusively industrial or professional use;

(25) 'availability of a substitute' means the ability of a substitute to be manufactured and delivered within a reasonable period of time as compared with the time required for manufacturing and delivering the substances listed in Annex II;

(26) 'reliability of a substitute' means the probability that an EEE using a substitute will perform a required function without failure under stated conditions for a stated period of time;

(27) 'spare part' means a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part;

(28) 'non-road mobile machinery made available exclusively for professional use' means machinery, with an on-board power source, the operation of which requires either mobility or continuous or semi-continuous movement between a succession of fixed working locations while working, and is made available exclusively for professional use.

*Article 4*

**Prevention**

1. Member States shall ensure that EEE placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, does not contain the substances listed in Annex II.

2. For the purposes of this Directive, no more than the maximum concentration value by weight in homogeneous materials as specified in Annex II shall be tolerated. The Commission shall adopt, by means of delegated acts in accordance with Article 20 and subject to the conditions laid down in Articles 21 and 22, detailed rules for complying with these maximum concentration values taking into account, inter alia, surface coatings.

[1] OJ L 204, 21.7.1998, p. 37.

[2] OJ L 189, 20.7.1990, p. 17.

3. Paragraph 1 shall apply to medical devices and monitoring and control instruments which are placed on the market from 22 July 2014, to in vitro diagnostic medical devices which are placed on the market from 22 July 2016 and to industrial monitoring and control instruments which are placed on the market from 22 July 2017.

4. Paragraph 1 shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of the following:

(a) EEE placed on the market before 1 July 2006;

(b) medical devices placed on the market before 22 July 2014;

(c) in vitro diagnostic medical devices placed on the market before 22 July 2016;

(d) monitoring and control instruments placed on the market before 22 July 2014;

(e) industrial monitoring and control instruments placed on the market before 22 July 2017;

(f) EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned.

5. Paragraph 1 shall not apply to reused spare parts, recovered from EEE placed on the market before 1 July 2006 and used in equipment placed on the market before 1 July 2016, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer.

6. Paragraph 1 shall not apply to the applications listed in Annexes III and IV.

*Article 5*

**Adaptation of the Annexes to scientific and technical progress**

1. For the purposes of adapting Annexes III and IV to scientific and technical progress, and in order to achieve the objectives set out in Article 1, the Commission shall adopt by means of individual delegated acts in accordance with Article 20 and subject to the conditions laid down in Articles 21 and 22, the following measures:

(a) inclusion of materials and components of EEE for specific applications in the lists in Annexes III and IV, provided that such inclusion does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 and where any of the following conditions is fulfilled:

— their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable,

— the reliability of substitutes is not ensured,

— the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

Decisions on the inclusion of materials and components of EEE in the lists in Annexes III and IV and on the duration of any exemptions shall take into account the availability of substitutes and the socioeconomic impact of substitution. Decisions on the duration of any exemptions shall take into account any potential adverse impacts on innovation. Life-cycle thinking on the overall impacts of the exemption shall apply, where relevant;

(b) deletion of materials and components of EEE from the lists in Annexes III and IV where the conditions set out in point (a) are no longer fulfilled.

2. Measures adopted in accordance with point (a) of paragraph 1 shall, for categories 1 to 7, 10 and 11 of Annex I, have a validity period of up to 5 years and, for categories 8 and 9 of Annex I, a validity period of up to 7 years. The validity periods are to be decided on a case-by-case basis and may be renewed.

For the exemptions listed in Annex III as at 21 July 2011, the maximum validity period, which may be renewed, shall, for categories 1 to 7 and 10 of Annex I, be 5 years from 21 July 2011 and, for categories 8 and 9 of Annex I, 7 years from the relevant dates laid down in Article 4(3), unless a shorter period is specified.

For the exemptions listed in Annex IV as at 21 July 2011, the maximum validity period, which may be renewed, shall be 7 years from the relevant dates laid down in Article 4(3), unless a shorter period is specified.

3. An application for granting, renewing or revoking an exemption shall be made to the Commission in accordance with Annex V.

4. The Commission shall:

(a) acknowledge receipt of an application in writing within 15 days of its receipt. The acknowledgement shall state the date of receipt of the application;

(b) inform the Member States of the application without delay and make the application and any supplementary information supplied by the applicant available to them;

(c) make a summary of the application available to the public;

(d) evaluate the application and its justification.

5. An application for renewal of an exemption shall be made no later than 18 months before the exemption expires.

The Commission shall decide on an application for renewal of an exemption no later than 6 months before the expiry date of the existing exemption unless specific circumstances justify other deadlines. The existing exemption shall remain valid until a decision on the renewal application is taken by the Commission.

6. In the event that the application for renewal of an exemption is rejected or that an exemption is revoked, the exemption shall expire at the earliest 12 months, and at the latest 18 months, after the date of the decision.

7. Before Annexes are amended, the Commission shall, inter alia, consult economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations and make the comments received publicly available.

8. The Commission shall adopt a harmonised format for applications referred to in paragraph 3 of this Article as well as comprehensive guidelines for such applications, taking into account the situation of SMEs. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).

*Article 6*

**Review and amendment of list of restricted substances in Annex II**

1. With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and amendment of the list of restricted substances in Annex II shall be considered by the Commission before 22 July 2014, and periodically thereafter on its own initiative or following the submission of a proposal by a Member State containing the information referred to in paragraph 2.

The review and amendment of the list of restricted substances in Annex II shall be coherent with other legislation related to chemicals, in particular Regulation (EC) No 1907/2006, and shall take into account, inter alia, Annexes XIV and XVII to that Regulation. The review shall use publicly available knowledge obtained from the application of such legislation.

In order to review and amend Annex II, the Commission shall take special account of whether a substance, including substances of very small size or with a very small internal or surface structure, or a group of similar substances:

(a) could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE;

(b) could give rise, given its uses, to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions;

(c) could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes;

(d) could be replaced by substitutes or alternative technologies which have less negative impacts.

During that review, the Commission shall consult interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations.

2. The proposals to review and amend the list of restricted substances, or a group of similar substances, in Annex II shall contain at least the following information:

(a) precise and clear wording of the proposed restriction;

(b) references and scientific evidence for the restriction;

(c) information on the use of the substance or the group of similar substances in EEE;

(d) information on detrimental effects and exposure in particular during waste EEE management operations;

(e) information on possible substitutes and other alternatives, their availability and reliability;

(f) justification for considering a Union-wide restriction as the most appropriate measure;

(g) socioeconomic assessment.

3. The measures referred to in this Article shall be adopted by the Commission by means of delegated acts in accordance with Article 20 and subject to the conditions laid down in Articles 21 and 22.

*Article 7*

**Obligations of manufacturers**

Member States shall ensure that:

(a) when placing EEE on the market, manufacturers ensure that it has been designed and manufactured in accordance with the requirements set out in Article 4;

(b) manufacturers 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 or have it carried out;

(c) where compliance of EEE with the applicable requirements has been demonstrated by the procedure referred to in point (b), manufacturers draw up an EU declaration of conformity and affix the CE marking on the finished product. Where other applicable Union legislation requires the application of a conformity assessment procedure which is at least as stringent, compliance with the requirements of Article 4(1) of this Directive may be demonstrated within the context of that procedure. A single technical documentation may be drawn up;

(d) manufacturers keep the technical documentation and the EU declaration of conformity for 10 years after the EEE has been placed on the market;

(e) manufacturers ensure that procedures are in place for series production to remain in conformity. Changes in product design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of EEE is declared shall be adequately taken into account;

(f) manufacturers keep a register of non-conforming EEE and product recalls, and keep distributors informed thereof;

(g) manufacturers ensure that their EEE bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the EEE does not allow it, that the required information is provided on the packaging or in a document accompanying the EEE;

(h) manufacturers indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. The address must indicate a single point at which the manufacturer can be contacted. Where other applicable Union legislation contains provisions for the affixing of the manufacturer's name and address which are at least as stringent, those provisions shall apply;

(i) manufacturers who consider or have reason to believe that EEE which they have placed on the market is not in conformity with this Directive immediately take the necessary corrective measures to bring that EEE into conformity, to withdraw it or recall it, if appropriate, and immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;

(j) manufacturers, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the EEE with this Directive, in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with this Directive of EEE which they have placed on the market.

*Article 8*

**Obligations of authorised representatives**

Member States shall ensure that:

(a) manufacturers have the possibility to appoint an authorised representative by written mandate. The obligations laid down in point (a) of Article 7 and the drawing up of technical documentation shall not form part of the authorised representative's mandate;

(b) an authorised representative performs the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

— keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authorities for 10 years following the placing on the market of the EEE,

— further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an EEE with this Directive,

— cooperate with the competent national authorities, at their request, on any action taken to ensure compliance with this Directive of EEE covered by their mandate.

*Article 9*

**Obligations of importers**

Member States shall ensure that:

(a) importers place only EEE that complies with this Directive on the Union market;

(b) importers, before placing an EEE on the market, ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer, and that they further ensure that the manufacturer has drawn up the technical documentation, that the EEE bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in points (f) and (g) of Article 7;

(c) where an importer considers or has reason to believe that an EEE is not in conformity with Article 4, that importer does not place the EEE on the market until it has been brought into conformity, and that that importer informs the manufacturer and the market surveillance authorities to that effect;

(d) importers indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. Where other applicable Union legislation contains provisions for the affixing of the importer's name and address which are at least as stringent, those provisions shall apply;

(e) importers, in order to ensure compliance with this Directive, keep a register of non-compliant EEE and EEE recalls, and keep distributors informed thereof;

(f) importers who consider or have reason to believe that an EEE which they have placed on the market is not in conformity with this Directive immediately take the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, as appropriate, and immediately inform the competent national authorities of

the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;

(g) importers keep, for 10 years following the placing on the market of the EEE, a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request;

(h) importers, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of an EEE with this Directive in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with this Directive of EEE which they have placed on the market.

*Article 10*

**Obligations of distributors**

Member States shall ensure that:

(a) when making an EEE available on the market, distributors act with due care in relation to the requirements applicable in particular by verifying that the EEE bears the CE marking, that it is accompanied by the required documents in a language which can be easily understood by consumers and other end-users in the Member State in which the EEE is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in points (g) and (h) of Article 7 and in point (d) of Article 9;

(b) where a distributor considers or has reason to believe that an EEE is not in conformity with Article 4, that distributor does not make the EEE available on the market until it has been brought into conformity, and that that distributor informs the manufacturer or the importer as well as the market surveillance authorities to that effect;

(c) distributors who consider or have reason to believe that an EEE which they have made available on the market is not in conformity with this Directive make sure that the corrective measures necessary to bring that EEE into conformity, to withdraw it or recall it, as appropriate, are taken and that they immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;

(d) distributors, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of EEE with this Directive, and that they cooperate with that authority, at its request, on any action taken to ensure the compliance with this Directive of the EEE which they have made available on the market.

*Article 11*

**Cases in which obligations of manufacturers apply to importers and distributors**

Member States shall ensure that an importer or distributor is considered a manufacturer for the purposes of this Directive and that he is subject to the obligations of the manufacturer under Article 7, where he places EEE on the market under his name or trademark or modifies EEE already placed on the market in such a way that compliance with the applicable requirements may be affected.

*Article 12*

**Identification of economic operators**

Member States shall ensure that economic operators, on request, identify the following to the market surveillance authorities, for 10 years following the placing on the market of the EEE:

(a) any economic operator who has supplied them with an EEE;

(b) any economic operator to whom they have supplied an EEE.

*Article 13*

**EU declaration of conformity**

1. The EU declaration of conformity shall state that it has been demonstrated that the requirements specified in Article 4 have been met.

2. The EU declaration of conformity shall have the model structure and shall contain the elements specified in Annex VI and shall be updated. It shall be translated into the language or languages required by the Member State on the market of which the product is placed or made available.

Where other applicable Union legislation requires the application of a conformity assessment procedure which is at least as stringent, compliance with the requirements of Article 4(1) of this Directive may be demonstrated within the context of that procedure. A single technical documentation may be drawn up.

3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the EEE with this Directive.

*Article 14*

**General principles of the CE marking**

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

*Article 15*

**Rules and conditions for affixing the CE marking**

1. The CE marking shall be affixed visibly, legibly and indelibly to the finished EEE or to its data plate. Where that is not possible or not warranted on account of the nature of the EEE, it shall be affixed to the packaging and to the accompanying documents.

2. The CE marking shall be affixed before the EEE is placed on the market.

3. Member States shall build upon existing mechanisms to ensure the correct application of the regime governing the CE marking and take appropriate action in the event of improper use of the CE marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.

*Article 16*

**Presumption of conformity**

1. In the absence of evidence to the contrary, Member States shall presume EEE bearing the CE marking to comply with this Directive.

2. Materials, components and EEE on which tests and measurements demonstrating compliance with the requirements of Article 4 have been performed, or which have been assessed, in accordance with harmonised standards, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to comply with the requirements of this Directive.

*Article 17*

**Formal objection to a harmonised standard**

1. Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements which it covers and which are set out in Article 4, the Commission or the Member State concerned shall bring the matter before the Committee set up pursuant to Article 5 of Directive 98/34/EC, giving its arguments. The Committee shall, after consulting the relevant European standardisation bodies, deliver its opinion without delay.

2. In the light of the Committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in or from the *Official Journal of the European Union*.

3. The Commission shall inform the European standardisation body concerned and, if necessary, request the revision of the harmonised standards concerned.

*Article 18*

**Market surveillance and controls of EEE entering the Union market**

Member States shall carry out market surveillance in accordance with Articles 15 to 29 of Regulation (EC) No 765/2008.

*Article 19*

**Committee procedure**

1. The Commission shall be assisted by the committee set up pursuant to Article 39 of Directive 2008/98/EC. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

*Article 20*

**Exercise of the delegation**

1. The powers to adopt the delegated acts referred to in Article 4(2), Article 5(1) and Article 6 shall be conferred on the Commission for a period of 5 years from 21 July 2011. The Commission shall draw up a report in respect of delegated powers at the latest 6 months before the end of the 5 year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 21.

2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3. The powers to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 21 and 22.

*Article 21*

**Revocation of the delegation**

1. The delegation of power referred to in Article 4(2), Article 5(1) and Article 6 may be revoked at any time by the European Parliament or by the Council.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of powers shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

*Article 22*

**Objections to delegated acts**

1. The European Parliament or the Council may object to a delegated act within a period of 2 months from the date of notification.

At the initiative of the European Parliament or the Council that period shall be extended by 2 months.

2. If, on expiry of the period referred to in paragraph 1, neither the European Parliament nor the Council has objected to the delegated act it shall be published in the *Official Journal of the European Union* and shall enter into force on the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If the European Parliament or the Council objects to the delegated act within the period referred to in paragraph 1, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

*Article 23*

**Penalties**

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 2 January 2013 and shall notify it without delay of any subsequent amendment affecting them.

*Article 24*

**Review**

1. No later than 22 July 2014 the Commission shall examine the need to amend the scope of this Directive in respect of the EEE referred to in Article 2, and shall present a report thereon to the European Parliament and the Council accompanied by a legislative proposal, if appropriate, with respect to any additional exclusions related to that EEE.

2. No later than 22 July 2021 the Commission shall carry out a general review of this Directive, and shall present a report to the European Parliament and the Council accompanied, if appropriate, by a legislative proposal.

*Article 25*

**Transposition**

1. Member States shall adopt and publish, by 2 January 2013, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 26*

**Repeal**

Directive 2002/95/EC as amended by the acts listed in Annex VII, Part A is repealed with effect from 3 January 2013 without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and application of the Directive set out in Annex VII, Part B.

References to the repealed acts shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VIII.

*Article 27*

**Entry into force**

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

*Article 28*

**Addressees**

This Directive is addressed to the Member States.

Done at Strasbourg, 8 June 2011.

| *For the European Parliament* | *For the Council* |
|---|---|
| *The President* | *The President* |
| J. BUZEK | GYŐRI E. |

*ANNEX I*

**Categories of EEE covered by this Directive**

1. Large household appliances.
2. Small household appliances.
3. IT and telecommunications equipment.
4. Consumer equipment.
5. Lighting equipment.
6. Electrical and electronic tools.
7. Toys, leisure and sports equipment.
8. Medical devices.
9. Monitoring and control instruments including industrial monitoring and control instruments.
10. Automatic dispensers.
11. Other EEE not covered by any of the categories above.

*ANNEX II*

**Restricted substances referred to in Article 4(1) and maximum concentration values tolerated by weight in homogeneous materials**

Lead (0,1 %)

Mercury (0,1 %)

Cadmium (0,01 %)

Hexavalent chromium (0,1 %)

Polybrominated biphenyls (PBB) (0,1 %)

Polybrominated diphenyl ethers (PBDE) (0,1 %)

*ANNEX III*

**Applications exempted from the restriction in Article 4(1)**

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

| Exemption | | Scope and dates of applicability |
|---|---|---|
| 3 | Mercury in cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFL and EEFL) for special purposes not exceeding (per lamp): | |
| 3(a) | Short length (≤ 500 mm) | No limitation of use until 31 December 2011; 3,5 mg may be used per lamp after 31 December 2011 |
| 3(b) | Medium length (> 500 mm and ≤ 1 500 mm) | No limitation of use until 31 December 2011; 5 mg may be used per lamp after 31 December 2011 |
| 3(c) | Long length (> 1 500 mm) | No limitation of use until 31 December 2011; 13 mg may be used per lamp after 31 December 2011 |
| 4(a) | Mercury in other low pressure discharge lamps (per lamp) | No limitation of use until 31 December 2011; 15 mg may be used per lamp after 31 December 2011 |
| 4(b) | Mercury in High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner) in lamps with improved colour rendering index Ra > 60: | |
| 4(b)-I | P ≤ 155 W | No limitation of use until 31 December 2011; 30 mg may be used per burner after 31 December 2011 |
| 4(b)-II | 155 W < P ≤ 405 W | No limitation of use until 31 December 2011; 40 mg may be used per burner after 31 December 2011 |
| 4(b)-III | P > 405 W | No limitation of use until 31 December 2011; 40 mg may be used per burner after 31 December 2011 |
| 4(c) | Mercury in other High Pressure Sodium (vapour) lamps for general lighting purposes not exceeding (per burner): | |
| 4(c)-I | P ≤ 155 W | No limitation of use until 31 December 2011; 25 mg may be used per burner after 31 December 2011 |
| 4(c)-II | 155 W < P ≤ 405 W | No limitation of use until 31 December 2011; 30 mg may be used per burner after 31 December 2011 |
| 4(c)-III | P > 405 W | No limitation of use until 31 December 2011; 40 mg may be used per burner after 31 December 2011 |
| 4(d) | Mercury in High Pressure Mercury (vapour) lamps (HPMV) | Expires on 13 April 2015 |
| 4(e) | Mercury in metal halide lamps (MH) | |
| 4(f) | Mercury in other discharge lamps for special purposes not specifically mentioned in this Annex | |
| 5(a) | Lead in glass of cathode ray tubes | |
| 5(b) | Lead in glass of fluorescent tubes not exceeding 0,2 % by weight | |

| Exemption | | Scope and dates of applicability |
|---|---|---|
| 6(a) | Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0,35 % lead by weight | |
| 6(b) | Lead as an alloying element in aluminium containing up to 0,4 % lead by weight | |
| 6(c) | Copper alloy containing up to 4 % lead by weight | |
| 7(a) | Lead in high melting temperature type solders (i.e. lead-based alloys containing 85 % by weight or more lead) | |
| 7(b) | Lead in solders for servers, storage and storage array systems, network infrastructure equipment for switching, signalling, transmission, and network management for telecommunications | |
| 7(c)-I | Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound | |
| 7(c)-II | Lead in dielectric ceramic in capacitors for a rated voltage of 125 V AC or 250 V DC or higher | |
| 7(c)-III | Lead in dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC | Expires on 1 January 2013 and after that date may be used in spare parts for EEE placed on the market before 1 January 2013 |
| 8(a) | Cadmium and its compounds in one shot pellet type thermal cut-offs | Expires on 1 January 2012 and after that date may be used in spare parts for EEE placed on the market before 1 January 2012 |
| 8(b) | Cadmium and its compounds in electrical contacts | |
| 9 | Hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0,75 % by weight in the cooling solution | |
| 9(b) | Lead in bearing shells and bushes for refrigerant-containing compressors for heating, ventilation, air conditioning and refrigeration (HVACR) applications | |
| 11(a) | Lead used in C-press compliant pin connector systems | May be used in spare parts for EEE placed on the market before 24 September 2010 |
| 11(b) | Lead used in other than C-press compliant pin connector systems | Expires on 1 January 2013 and after that date may be used in spare parts for EEE placed on the market before 1 January 2013 |
| 12 | Lead as a coating material for the thermal conduction module C-ring | May be used in spare parts for EEE placed on the market before 24 September 2010 |
| 13(a) | Lead in white glasses used for optical applications | |
| 13(b) | Cadmium and lead in filter glasses and glasses used for reflectance standards | |
| 14 | Lead in solders consisting of more than two elements for the connection between the pins and the package of microprocessors with a lead content of more than 80 % and less than 85 % by weight | Expired on 1 January 2011 and after that date may be used in spare parts for EEE placed on the market before 1 January 2011 |

| Exemption | | Scope and dates of applicability |
|---|---|---|
| 15 | Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages | |
| 16 | Lead in linear incandescent lamps with silicate coated tubes | Expires on 1 September 2013 |
| 17 | Lead halide as radiant agent in high intensity discharge (HID) lamps used for professional reprography applications | |
| 18(a) | Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as speciality lamps for diazoprinting reprography, lithography, insect traps, photochemical and curing processes containing phosphors such as SMS ($(Sr,Ba)_2MgSi_2O_7$:Pb) | Expired on 1 January 2011 |
| 18(b) | Lead as activator in the fluorescent powder (1 % lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP ($BaSi_2O_5$:Pb) | |
| 19 | Lead with PbBiSn-Hg and PbInSn-Hg in specific compositions as main amalgam and with PbSn-Hg as auxiliary amalgam in very compact energy saving lamps (ESL) | Expires on 1 June 2011 |
| 20 | Lead oxide in glass used for bonding front and rear substrates of flat fluorescent lamps used for Liquid Crystal Displays (LCDs) | Expires on 1 June 2011 |
| 21 | Lead and cadmium in printing inks for the application of enamels on glasses, such as borosilicate and soda lime glasses | |
| 23 | Lead in finishes of fine pitch components other than connectors with a pitch of 0,65 mm and less | May be used in spare parts for EEE placed on the market before 24 September 2010 |
| 24 | Lead in solders for the soldering to machined through hole discoidal and planar array ceramic multilayer capacitors | |
| 25 | Lead oxide in surface conduction electron emitter displays (SED) used in structural elements, notably in the seal frit and frit ring | |
| 26 | Lead oxide in the glass envelope of black light blue lamps | Expires on 1 June 2011 |
| 27 | Lead alloys as solder for transducers used in high-powered (designated to operate for several hours at acoustic power levels of 125 dB SPL and above) loudspeakers | Expired on 24 September 2010 |
| 29 | Lead bound in crystal glass as defined in Annex I (Categories 1, 2, 3 and 4) of Council Directive 69/493/EEC [1] | |
| 30 | Cadmium alloys as electrical/mechanical solder joints to electrical conductors located directly on the voice coil in transducers used in high-powered loudspeakers with sound pressure levels of 100 dB (A) and more | |
| 31 | Lead in soldering materials in mercury free flat fluorescent lamps (which, e.g. are used for liquid crystal displays, design or industrial lighting) | |
| 32 | Lead oxide in seal frit used for making window assemblies for Argon and Krypton laser tubes | |

| Exemption | | Scope and dates of applicability |
|---|---|---|
| 33 | Lead in solders for the soldering of thin copper wires of 100 μm diameter and less in power transformers | |
| 34 | Lead in cermet-based trimmer potentiometer elements | |
| 36 | Mercury used as a cathode sputtering inhibitor in DC plasma displays with a content up to 30 mg per display | Expired on 1 July 2010 |
| 37 | Lead in the plating layer of high voltage diodes on the basis of a zinc borate glass body | |
| 38 | Cadmium and cadmium oxide in thick film pastes used on aluminium bonded beryllium oxide | |
| 39 | Cadmium in colour converting II-VI LEDs (< 10 μg Cd per $mm^2$ of light-emitting area) for use in solid state illumination or display systems | Expires on 1 July 2014 |

([1]) OJ L 326, 29.12.1969, p. 36.

*ANNEX IV*

**Applications exempted from the restriction in Article 4(1) specific to medical devices and monitoring and control instruments**

Equipment utilising or detecting ionising radiation

1. Lead, cadmium and mercury in detectors for ionising radiation.

2. Lead bearings in X-ray tubes.

3. Lead in electromagnetic radiation amplification devices: micro-channel plate and capillary plate.

4. 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.

5. Lead in shielding for ionising radiation.

6. Lead in X-ray test objects.

7. Lead stearate X-ray diffraction crystals.

8. Radioactive cadmium isotope source for portable X-ray fluorescence spectrometers.

Sensors, detectors and electrodes

1a. Lead and cadmium in ion selective electrodes including glass of pH electrodes.

1b. Lead anodes in electrochemical oxygen sensors.

1c. Lead, cadmium and mercury in infra-red light detectors.

1d. Mercury in reference electrodes: low chloride mercury chloride, mercury sulphate and mercury oxide.

Others

9. Cadmium in helium-cadmium lasers.

10. Lead and cadmium in atomic absorption spectroscopy lamps.

11. Lead in alloys as a superconductor and thermal conductor in MRI.

12. Lead and cadmium in metallic bonds to superconducting materials in MRI and SQUID detectors.

13. Lead in counterweights.

14. Lead in single crystal piezoelectric materials for ultrasonic transducers.

15. Lead in solders for bonding to ultrasonic transducers.

16. Mercury in very high accuracy capacitance and loss measurement bridges and in high frequency RF switches and relays in monitoring and control instruments not exceeding 20 mg of mercury per switch or relay.

17. Lead in solders in portable emergency defibrillators.

18. Lead in solders of high performance infrared imaging modules to detect in the range 8-14 μm.

19. Lead in Liquid crystal on silicon (LCoS) displays.

20. Cadmium in X-ray measurement filters.

*ANNEX V*

**Applications for granting, renewing and revoking exemptions as referred to in Article 5**

Applications for exemptions, renewal of exemptions or, *mutatis mutandis,* for revoking an exemption may be submitted by a manufacturer, the authorised representative of a manufacturer, or any economic operator in the supply chain and shall include at least the following:

(a) the name, address and contact details of the applicant;

(b) information on the material or component and the specific uses of the substance in the material and component for which an exemption, or its revocation, is requested and its particular characteristics;

(c) verifiable and referenced justification for an exemption, or its revocation, in line with the conditions established in Article 5;

(d) an analysis of possible alternative substances, materials or designs on a life-cycle basis, including, when available, information about independent research, peer-review studies and development activities by the applicant and an analysis of the availability of such alternatives;

(e) information on the possible preparation for reuse or recycling of materials from waste EEE, and on the provisions relating to the appropriate treatment of waste according to Annex II to Directive 2002/96/EC;

(f) other relevant information;

(g) the proposed actions to develop, request the development and/or to apply possible alternatives including a timetable for such actions by the applicant;

(h) where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;

(i) when applying for an exemption, proposal for a precise and clear wording for the exemption;

(j) a summary of the application.

*ANNEX VI*

**EU DECLARATION OF CONFORMITY**

1. No … (unique identification of the EEE):

2. Name and address of the manufacturer or his authorised representative:

3. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):

4. Object of the declaration (identification of EEE allowing traceability. It may include a photograph, where appropriate):

5. The object of the declaration described above is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (*):

6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:

7. Additional information:

Signed for and on behalf of: .....

(place and date of issue):

(name, function) (signature):

(*) OJ L 174, 1.7.2011, p. 88.

*ANNEX VII*

PART A

**Repealed Directive with its successive amendments**

(referred to in Article 26)

| | |
|---|---|
| Directive 2002/95/EC of the European Parliament and of the Council | (OJ L 37, 13.2.2003, p. 19). |
| Commission Decision 2005/618/EC | (OJ L 214, 19.8.2005, p. 65). |
| Commission Decision 2005/717/EC | (OJ L 271, 15.10.2005, p. 48). |
| Commission Decision 2005/747/EC | (OJ L 280, 25.10.2005, p. 18). |
| Commission Decision 2006/310/EC | (OJ L 115, 28.4.2006, p. 38). |
| Commission Decision 2006/690/EC | (OJ L 283, 14.10.2006, p. 47). |
| Commission Decision 2006/691/EC | (OJ L 283, 14.10.2006, p. 48). |
| Commission Decision 2006/692/EC | (OJ L 283, 14.10.2006, p. 50). |
| Directive 2008/35/EC of the European Parliament and of the Council | (OJ L 81, 20.3.2008, p. 67). |
| Commission Decision 2008/385/EC | (OJ L 136, 24.5.2008, p. 9). |
| Commission Decision 2009/428/EC | (OJ L 139, 5.6.2009, p. 32). |
| Commission Decision 2009/443/EC | (OJ L 148, 11.6.2009, p. 27). |
| Commission Decision 2010/122/EU | (OJ L 49, 26.2.2010, p. 32). |
| Commission Decision 2010/571/EU | (OJ L 251, 25.9.2010, p. 28). |

PART B

**List of time-limits for transposition into national law**

(referred to in Article 26)

| Directive | Deadline for transposition |
|---|---|
| 2002/95/EC | 12 August 2004 |
| 2008/35/EC | — |

*ANNEX VIII*

**Correlation table**

| Directive 2002/95/EC | This Directive |
|---|---|
| Article 1 | Article 1 |
| Article 2(1) | Article 2(1), 2(2), Annex I |
| Article 2(2) | Article 2(3) |
| Article 2(3) | Article 2(4), introductory wording |
| — | Article 2(4) |
| Article 3(a) | Article 3(1),(2) |
| Article 3(b) | — |
| — | Article 3(6)-(28) |
| Article 4(1) | Article 4(1), Annex II |
| — | Article 4(3)-(4) |
| Article 4(2) | Article 4(6) |
| Article 4(3) | — |
| Article 5(1), introductory wording | Article 5(1), introductory wording |
| Article 5(1)(a) | Article 4(2) |
| Article 5(1)(b) | Article 5(1)(a), first and third indents |
| — | Article 5(1)(a), second indent<br>Article 5(1)(a), final paragraph |
| Article 5(1)(c) | Article 5(1)(b) |
| — | Article 5(2)<br>Article 5(3)-(6) |
| Article 5(2) | Article 5(7) |
| — | Article 5(8) |
| Article 6 | Article 6 |
| — | Article 7-18 |
| Article 7 | Articles 19-22 |
| Article 8 | Article 23 |
| Article 9 | Article 25 |
| — | Article 26 |
| Article 10 | Article 27 |
| Article 11 | Article 28 |
| — | Annexes I-II |
| Annex, points 1-39 | Annex III, points 1-39 |
| — | Annexes IV, V, VI-VIII |

# ANNEX D: ORGALIME MEMBER ASSOCIATIONS

**AUSTRIA**
**FEEI** Fachverband der Elektro- und Elektronikindustrie Österreichs
Mariahilfer Strasse 37-39 – 1060 Vienna
Tel : (43) 1 588 39 0 – Fax : (43) 1 586 69 71
**FMMI** Fachverband Maschinen & Metallwaren Industrie
Wiedner Hauptstrasse 63, Postfach 335 – 1045 Vienna
Tel : (43) 5 90 900 3482 – Fax : (43) 1 505 10 20

**BELGIUM**
**AGORIA** La fédération de l'industrie technologique
De federatie van de technologische industrie
Diamant Building, Bd. A. Reyers 80 – 1030 Brussels
Tel : (32) 2 706 78 00 – Fax : (32) 2 706 78 01

**BULGARIA**
**BASSEL** Bulgarian Association of Electrical Engineering and Electronics
P.O. Box 76 – 1407 Sofia
Tel: (359) 2 963 3532 or 963 3437 - Fax: (359) 2 963 0727

**DENMARK**
**DI** Confederation of Danish Industries
H.C. Andersen Boulevard 18 – 1787 CopenhagenV
Tel : (45) 33 77 33 77 – Fax : (45) 33 77 33 00

**FINLAND**
**The Federation of Finnish Technology Industries**
Eteläranta 10 – 00131 Helsinki 13
Tel : (358) 9 19231 – Fax : (358) 9 624462

**FRANCE**
**FIEEC** Fédération des Industries Electriques, Electroniques et de Communication
Rue Hamelin 11-17 – 75783 Paris Cedex 16
Tel : (33) 1 45 05 70 70 – Fax : (33) 1 45 53 03 93
**FIM** Fédération des Industries Mécaniques
Maison de la Mécanique, rue Louis Blanc 39-41 – 92400 Courbevoie
Tel : (33) 1 47 17 60 00 – Fax : (33) 1 47 17 60 16

**GERMANY**
**VDMA** Verband Deutscher Maschinen- und Anlagenbau e.V.
Lyoner Strasse 18, Postfach 71 08 64 – 60582 Frankfurt/Main
Tel : (49) 69 6603 0 – Fax : (49) 69 6603 1511
**WSM** Wirtschaftsverband Stahl- und Metallverarbeitung e.V.
Kaiserswerther Strasse 137 – 40474 Düsseldorf
Tel : (49) 211 4564 101 – Fax : (49) 211 4564 169
**ZVEI** Zentralverband Elektrotechnik- und Elektronikindustrie e.V.
Lyoner Strasse 9, Postfach 70 12 61 – 60528 Frankfurt/Main
Tel : (49) 69 6302 0 – Fax : (49) 69 6302 317

**IRELAND**
**IEEF** Irish Engineering Enterprises Federation
Confederation House, 84-86 Lower Baggot Street – Dublin 2
Tel: (353) 1 605 1676 – Fax : (353) 1 638 1676

**ITALY**
**ANIE** Federazione Nazionale Industrie Elettrotecniche ed Elettroniche
Viale Lancetti 43, 20158 Milano
Tel : (39) 02 326 41 – Fax : (39) 02 326 4212
**ANIMA** Federazione delle Associazioni Nazionali dell' Industria Meccanica varia ed affine Via A. Scarsellini, 13 – 20161 Milano
Tel : (39) 02 4541 8500 – Fax : (39) 02 4541 8545

**LATVIA**
**Association of Mechanical Engineering and Metalworking Industries of Latvia**
Ezermalas 6 - 1006 Riga
Tel : (371) 755 48 25 - Fax : (371) 708 97 76

**LITHUANIA**
**LINPRA** The Engineering Industries Association of Lithuania
Savanoriupr 176 - 03154 Vilnius
Tel : (370) 5 231 25 20 - Fax : (370) 5 231 25 20

**LUXEMBOURG**
**ILTM** Industrie Luxembourgeoise de la Technologie du Métal
B.P. 1304 – 1013 Luxembourg
Tel : (352) 43 53 661 – Fax (352) 43 23 28

**THE NETHERLANDS**
**FME-CWM** Association of Enterprises in the Technological Industrial Sector
Boerhaavelaan 40, Postbus 190 – 2713 AD Zoetermeer
Tel : (31) 79 353 1100 – Fax : (31) 79 353 1365
**METAALUNIE** Nederlandse Organisatie van Ondernemers in het Midden- en Kleinbedrijf in de Metaal Postbus 2600 – 3430 GA Nieuwegein
Tel : (31) 3060 53344 – Fax : (31) 3060 53122

**NORWAY**
**Norsk Industri** P.O. Box 7072 Majorstua – 0306 Oslo 3
Tel : (47) 22 59 0000 – Fax : (47) 22 59 0001

**POLAND**
**Polish Economic Chamber of Electrotechnics**
ul.Szubińska 17, 85-312 Bydgoszcz
Tel/Fax : (48) 52 375 45 71

**PORTUGAL**
**AIMMAP** Associação dos Industriais Metalurgicos, Metalomecanicos e Afins de Portugal
Rua dos Platanos 197 - 4100 Porto
Tel : (351) 22 616 68 60 - Fax : (351) 22 610 74 73
**ANEMM** Associação Nacional das Empresas Metalúrgicas e Electromecânicas
Estrada do Paço do Lumiar, Polo Tecnologico de Lisboa, Lote 13 – 1600-485 Lisbon
Tel : (351) 21 715 21 72 - Fax : (351) 21 715 04 03

**SLOVENIA**
**GZS-MPIA** Metal Processing Industry Association
C/o Chamber of Commerce and Industry of Slovenia
Dimiceva 13 - 1504 Ljubljana
Tel : (386) 1 58 98 000 – Fax : (386) 1 58 98 100

**SPAIN**
**CONFEMETAL** Confederación Española de Organizaciones Empresariales del Metal : Principe de Vergara 74 – 28006 Madrid
Tel : (34) 91 562 5590 - Fax : (34) 91 562 8477
**SERCOBE** Asociación Nacional de Fabricantes de Bienes de Equipo
Calle Jorge Juan 47 – 28001 Madrid
Tel: (34)91 435 7240 – Fax : (34) 91 577 0910

**SWEDEN**
**TEKNIKFORETAGEN** The Association of Swedish Engineering Industries
P.O. Box 5510 – 114 85 Stockholm
Tel: (46)8 782 0800 – Fax : (46) 8 782 0900

**SWITZERLAND**
**SWISSMEM** Schweizer Maschinen-, Elektro- und Metallindustrie
Kirchenweg 4 – 8032 Zürich Tel : (41) 44 384 4111 – Fax : (41) 44 384 4242

**UNITED KINGDOM**
**BEAMA** Federation of British Electrotechnical and Allied Manufacturers – Associations Ltd
Westminster Tower, 3 Albert Embankment – London SE1 7SL
Tel : (44) 207 793 3000 – Fax : (44) 207 793 3003
**EAMA** Engineering and Machinery Alliance
62, Bayswater Road - London W2 3PS
Tel: (44) 20 7298 6450 – Fax: (44) 20 7298 6434
**GAMBICA** Association for Instrumentation, Control, Automation and Laboratory Technology
Broadwall House, 21 Broadwall - London SE1 9PL
Tel: (44) 207 642 8080 – Fax: (44) 207 642 8096

**ASSOCIATE MEMBER**

**CROATIA**
**CEA** Croatian Employers Association
Ulica Pavla Hatza 12 – 10000 Zagreb, Hrvatska
Tel: (385) 1 48 97 571 – Fax : (385) 1 48 97 581

**EUROPE**
**CEIR European Committee for the Valve Industry**
Diamant Building, 80 Boulevard A Reyers, 1030 Brussels, Belgium Tel: (32) 2 706 87 30 - Fax: (32) (32) 2 706 87 50

**CELMA Federation of National Manufacturers Associations for Luminaires and Electrotechnical Components for Luminaires in the European Union**
Diamant Building, 80 Boulevard A Reyers, 1030 Brussels, Belgium Tel: (32) 2 706 87 12 - Fax: (32) 2 706 87 13

**EFCEM European Federation of Catering Equipment Manufacturers**
General Secretariat is located in: CECED Italia, Via M. Bandello, 5 – 20123 Milano Tel. +39 02 43518826

**EGMF European Garden Machinery Federation**
Diamant Building, 80 Boulevard A Reyers, 1030 Brussels, Belgium Tel: (32) 2 706 82 37 & Tel: (32) 2 706 82 30 - Fax: (32) 2 706 82 50

**EUROPUMP**
**European Pump Industry**
Diamant Building, 80 Boulevard A Reyers, 1030 Brussels, Belgium
Tel: (32) 2 706 82 37 & Tel: (32) 2 706 82 30 - Fax: (32) 2 706 82 50

# ANNEX E: ORGALIME PUBLICATIONS

**All publications are available in English, French and German unless otherwise stated.**
**Details of these publications can be found on our website at www.orgalime.org**
**Information on our licence agreements can be found on http://licensing.orgalime.org**

## Model Forms

- Exclusive agreement with agents abroad – June 2011 (3)
- Agency Contract - International agency contract on an exclusive basis – January 2002 (5)
- Exclusive agreement with distributors abroad – May 2011 (3)
- Exclusive agreement with distributors abroad – June 2006
- International technology licence agreement (Inside EU/EEA version) – January 2005
- International technology licence agreement (Outside EU/EEA version) – June 2006
- Original equipment manufacturer contract (OEM contract) – August 2007
- Consortium agreement – February 1995
- Non-Disclosure Agreement – January 2008 (9)
- Model Contract for Technical Work on Site – January 2010 (2)

## Guides

- Drawings and technical documents - Ownership and protection against improper use – June 1993 (3)
- Guide for drawing up an international development contract – September 1999 (2)
- Security for payment in credit sales – December 1999 (3)
- Guide on S 2000 – September 2000 (2)
- Understanding WEEE & RoHS Guide – April 2003 (3)
- European Competition Law in Practice – 30 key points – May 2004 (2)
- Co-operation Agreements: A short guide to the creation of a joint venture – June 2004 (3)
- Guide to Defect Liability in Europe – April 2005 (3)
- Guide to contractual options for B-2-B equipment under WEEE – March 2006 (3)

**Guides available for free download from our publications website http://publications.orgalime.org:**

- WEEE & RoHS Scope Guide – January 2006 (3)
- Orgalime Guide: Assembly under PED – May 2006 (3)
- Orgalime RoHS Guide, March 2006, updated January 2007 (3)
- Pressure Equipment Directive – May 1999 – Updated April 2008 (3)
- REACH Guide – May 2007 – Last Update October 2009 (3)
- Orgalime Guide on Recast RoHS Directive – July 2011 (3)

## Conditions of contract

- General conditions for the supply of mechanical, electrical and associated electronic products –S 2012 – March 2012 (8)
- Supplementary conditions for the supervision of erection of mechanical, electrical and electronic products – S 2000 S – August 2000 (7)
- General conditions for Computer Software – SW 01 – March 2001 (7)
- General conditions for Maintenance – M 2000 – September 2000 (6)
- General conditions for the supply and erection of mechanical, electrical and electronic products –SE 01 – September 2001 (4)
- General conditions for the manufacture and supply of specially designed components –SC 06 – April 2006
- General conditions for series processing – SP99 – December 1999 (5)
- General conditions for the repair of machinery and equipment – R 02 – July 2002 (5)
- Turnkey Contract for Industrial Works – March 2003 (1)(5)

(1) English & French only
(2) English & German only
(3) English only
(4) Also in Spanish, Italian, Portuguese, Dutch, Hungarian, Swedish & Russian
(5) Also in Spanish
(6) Also in Spanish & Portuguese
(7) Also in Spanish, Italian & Portuguese
(8) Also in Danish, Italian, Portuguese, Spanish & Swedish
(9) Also in Danish, Dutch, Finnish, Italian, Spanish& Swedish
(More languages available soon)

# ANNEX F: LIST OF EUROPEAN SECTOR ORGANISATIONS PARTICIPATING IN THE DRAFTING OF THIS GUIDE

**CECED** – European Committee of Domestic Equipment Manufacturers

**COCIR –** The Radiological, Electromedical and Healthcare IT industry in Europe

**ELC –** European Lamp Companies Federation

**ESMIG** – The European Smart Metering Industry Group

**EUROPUMP** – The Voice of the European Pump Industry

**PNEUROP** – European Committee for Compressed Air, Gas and Vacuum Industry

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Editeur responsable: Adrian Harris, Director General

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